

EXHIBIT B

**THIS EXHIBIT CONTAINS CONFIDENTIAL OR
RESTRICTED CONFIDENTIAL INFORMATION
AND HAS BEEN SERVED VIA EMAIL.**

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE DISTRICT OF NEW JERSEY
3 CAMDEN VICINAGE
4 -----)
5 IN RE: VALSARTAN, LOSARTAN,) MDL No. 2875
6 AND IRBESARTAN PRODUCTS)
7 LIABILITY LITIGATION) Civil No. 19-2875
8) (RBK/JS)
9 -----)
10 THIS DOCUMENT RELATES TO ALL)
11 CASES) HON. ROBERT B. KUGLER
12)
13 -----)
14 - CONFIDENTIAL INFORMATION -
15 SUBJECT TO PROTECTIVE ORDER

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VIDEOTAPED DEPOSITION OF
JOHN M. FLACK, MD, MPH, FAHA, MACP, FASH
September 28, 2021

Remote videotaped deposition of JOHN M.
FLACK, MD, MPH, FAHA, MACP, FASH, commencing at 9:09
a.m., on the 28th day of September, 2021, before
Juliana F. Zajicek, Registered Professional Reporter,
Certified Shorthand Reporter and Certified Realtime
Reporter.

GOLKOW LITIGATION SERVICES
877.370.3377 ph | 917.591.5672 fax
deps@golkow.com

<p style="text-align: right;">Page 2</p> <p>1 A P P E A R A N C E S : 2 (ALL PARTIES APPEARED REMOTELY)</p> <p>3 ON BEHALF OF THE PLAINTIFFS: 4 SLACK DAVIS SANGER LLP 5 6001 Bold Ruler Way, Suite 100 6 Austin, Texas 78746 7 512-795-8686 8 BY: JOHN R. DAVIS, ESQ. 9 jdavis@slackdavis.com 10 -and- 11 KANNER & WHITELEY, LLC 12 701 Camp Street 13 New Orleans, Louisiana 70130 14 504-524-5777 15 BY: LAYNE HILTON, ESQ. 16 l.hilton@kanner-law.com; 17 DAVID J. STANOCH, ESQ. 18 d.stanoch@kanner-law.com 19 -and- 20 HOLLIS LAW FIRM 21 8101 College Boulevard, Suite 260 22 Overland Park, Kansas 66210 23 800-701-3672 24 BY: IRIS SIMPSON, ESQ. iris@hollislawfirm.com; C. BRETT VAUGHN, ESQ. brett@hollislawfirm.com -and- 25 MAZIE SLATER KATZ & FREEMAN, LLC 26 103 Eisenhower Parkway 27 Roseland, New Jersey 07068 28 973-228-9898 29 BY: ADAM SLATER, ESQ. 30 aslater@mazieslatter.com 31 -and-</p>	<p style="text-align: right;">Page 4</p> <p>1 A P P E A R A N C E S : 2 (ALL PARTIES APPEARED REMOTELY)</p> <p>3 ON BEHALF OF DEFENDANTS CVS PHARMACY, INC. and RITE 4 AID CORPORATION: 5 BARNES & THORNBURG LLP 6 11 South Meridian Street 7 Indianapolis, Indiana 46204-3535 8 317-231-6491 9 BY: KARA M. KAPKE, ESQ. kkapke@btlaw.com 10 -and- 11 ON BEHALF OF DEFENDANTS TEVA PHARMACEUTICAL 12 INDUSTRIES, LTD., TEVA PHARMACEUTICALS SA, INC., 13 ACTAVIS LLC, and ACTAVIS PHARMA, INC.: 14 GREENBERG TRAURIG, LLP 15 Terminus 200 16 3333 Piedmont Road NE, Suite 2500 17 Atlanta, Georgia 30305 18 678-553-2100 19 BY: STEVEN M. HARKINS, ESQ. harkinss@gtlaw.com 20 -and- 21 GREENBERG TRAURIG, LLP 22 2101 L Street, N.W., Suite 1000 23 Washington, D.C. 20037 24 202-530-8587 BY: STEPHEN T. FOWLER, ESQ. fowlerst@gtlaw.com -and- 25 WALSH PIZZI O'REILLY FALANGA, LLP 26 Three Gateway Center 27 100 Mulberry Street, 15th Floor 28 Newark, New Jersey 07102 29 973-757-1017 30 BY: CHRISTINE I. GANNON, ESQ. cgannon@walsh.law</p>
<p style="text-align: right;">Page 3</p> <p>1 A P P E A R A N C E S : 2 (ALL PARTIES APPEARED REMOTELY)</p> <p>3 ON BEHALF OF THE PLAINTIFFS: (Continued) 4 FARR LAW FIRM, P.A. 99 Nesbit Street 5 Punta Gorda, Florida 33950 6 941-639-1158 7 BY: GEORGE T. WILLIAMSON, ESQ. gwilliamson@farr.com -and- 8 HONIK LLC 9 1515 Market Street, Suite 1100 10 Philadelphia, Pennsylvania 19102 11 267-535-1300 12 BY: RUBEN HONIK, ESQ. ruben@honiklaw.com 13 -and- 14 ON BEHALF OF DEFENDANT ALBERTSON'S LLC: 15 BUCHANAN INGERSOLL & ROONEY PC 16 1700 K Street, N.W., Suite 300 17 Washington, D.C. 20006-3807 18 202-452-7318 19 BY: ASHLEY D. JONES, ESQ. ashley.jones@bipc.com -and- 20 BUCHANAN INGERSOLL & ROONEY PC 21 227 West Trade Street, Suite 600 22 Charlotte, North Carolina 28202 23 704-444-3475 24 BY: CHRISTOPHER B. HENRY, ESQ. christopher.henry@bipc.com</p>	<p style="text-align: right;">Page 5</p> <p>1 A P P E A R A N C E S : 2 (ALL PARTIES APPEARED REMOTELY)</p> <p>3 ON BEHALF OF DEFENDANTS ZHEJIANG HUAHAI PHARMACEUTICAL 4 CO., LTD, PRINSTON PHARMACEUTICAL INC, HUAHAI U.S., 5 INC, AND SOLCO HEALTHCARE US, LLC: 6 DUANE MORRIS, LLP 7 100 High Street, Suite 2400 8 Boston, Massachusetts 02110-1724 857-488-4267 7 BY: LAUREN A. APPEL, ESQ laappel@duanemorris.com 8 -and- 9 ON BEHALF OF DEFENDANTS AUROBINDO PHARMA LTD , 10 AUROLIFE PHARMA LLC, and AUROBINDO PHARMA USA, INC : 11 CIPRIANI & WERNER, P.C 12 450 Sentry Parkway 13 Blue Bell, Pennsylvania 19422 14 610-567-0700 15 BY: JESSICA M. HEINZ, ESQ jheinz@c-wlaw.com 16 -and- 17 ON BEHALF OF DEFENDANT MYLAN PHARMACEUTICALS, INC : 18 PIETRAGALLO GORDON ALFANO BOSICK & 19 RASPANTI, LLP 20 One Oxford Centre 21 Pittsburgh, Pennsylvania 15219 22 412-263-1840 23 BY: JASON M. REEFER, ESQ jmr@pietragallo.com 19 -and- 20 ON BEHALF OF DEFENDANT SCIEGEN PHARMACEUTICALS, INC : 21 HINSHAW & CULBERTSON LLP 22 53 State Street, 27th Floor 23 Boston, Massachusetts 02109 24 617-213-7045 23 BY: GEOFFREY M. COAN, ESQ gcoan@hinshawlaw.com</p>

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1 ALSO PRESENT: 2 MR. BRAD MATT A. 3 4 VIDEOGRAPHER: 5 CAROLIN DE LA ROSA 6 Golkow Litigation Services 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	1 E X H I B I T S (Continued) 2 PLAINTIFF-FLACK EXHIBIT 3 No. 5 Department of Justice, U.S. MARKED FOR ID 4 Attorney's Office, Southern 5 District of New York Press Release 6 dated Wednesday, July 1, 2020, 7 titled: "Acting Manhattan U.S. 8 Attorney Announces \$678 Million 9 Settlement of Fraud Lawsuit Against Novartis Pharmaceuticals For Operating Sham Speaker Programs Through Which It Paid Over \$100 Million to Doctors To Unlawfully Induce Them To Prescribe Novartis Drugs" 10 No. 6 E-mail dated 4/12/06 from Roger 90 Stojeba to Melissa Ostendorf, Subject: Re: National speakers up for grabs!; NPCLSV_LIT002333074 11 12 No. 7 E-mail chain dated 3/29/06 from 96 Jason Barnes to Jill Gross, among others; NPCLSV_LIT003753068 - 070 13 14 No. 8 Journal of Human Hypertension, 101 Article titled "Efficacy and safety of initial combination therapy with amlodipine/valsartan compared with amlodipine monotherapy in black patients with stage 2 hypertension: The EX-STAND study," by Flack, et al. 15 No. 9 Original Research, Therapeutic 117 Advances in Cardiovascular Disease, titled "Individualizing hypertension treatment with impedance cardiography: A meta-analysis of published trials," by Ferrario, Flack, et al. 16 17 18 19 No. 10 John M. Flack, M.D., MPH, List of 124 Materials Considered 20 21 22 23 24
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1 I N D E X 2 3 WITNESS: PAGE: 4 JOHN M. FLACK, MD, MPH, FAHA, MACP, FASH 5 6 EXAM BY MR. DAVIS..... 10 7 EXAM BY MR. FOWLER..... 187 8 FURTHER EXAM BY MR. DAVIS..... 209 9 10 ***** 11 12 E X H I B I T S 13 PLAINTIFF-FLACK EXHIBIT MARKED FOR ID 14 No. 1 Defendants' Responses and 13 Objections to Plaintiffs' Amended 15 Notice of Videotaped Deposition of John M. Flack, MD, MPH, FAHA, 16 MACP, FASH 17 No. 2 Invoice, Date of Service: Through 22 July 20, 2021, Invoice Date: July 18 21, 2021 19 No. 3 Expert Report of John Flack, M.D., 49 M.P.H. 20 21 No. 4 Curriculum Vitae - John M. Flack, 60 MD, MPH, FAHA, MACP, FASH 22 23 24	1 E X H I B I T S (Continued) 2 PLAINTIFF-FLACK EXHIBIT MARKED FOR ID 3 No. 11 Scientific Reports, Article titled 157 "Association between blood 4 pressure and risk of cancer development: A systematic review 5 and meta-analysis of observational studies," by Seretis, et al. 6 7 No. 12 Supplemental list of materials 192 considered 8 No. 13 Flash drive containing reliance 193 material 9 10 No. 14 Article published in the 202 Pharmacology & Therapeutics Journal: "Carcinogenesis: Failure 11 of resolution of inflammation?" By Anna Fishbein, et al. 12 13 No. 15 Invoice, Date of Service: Through 220 July 21 - September 7, 2021, Invoice Date: September 7, 2021 14 15 16 17 18 19 20 21 22 23 24

<p>1 THE VIDEOGRAPHER: We are now on the record. My 2 name is Carolin De La Rosa, a videographer for Golkow 3 Litigation Services. Today's date is September 28th, 4 2021, and the time is 9:09 a.m.</p> <p>5 This deposition is being held In the 6 Matter of Valsartan, Losartan, and Irbesartan Products 7 Liability Litigation.</p> <p>8 The deponent today is Dr. John Flack.</p> <p>9 All parties are noted on the stenographic 10 record.</p> <p>11 Will the court reporter please swear in 12 the witness.</p> <p>13 (WHEREUPON, the witness was duly 14 sworn.)</p> <p>15 JOHN M. FLACK, 16 MD, MPH, FAHA, MACP, FASH, 17 called as a witness herein, having been first duly 18 sworn, was examined and testified as follows:</p> <p>19 EXAMINATION 20 BY MR. DAVIS:</p> <p>21 Q. Good morning, Dr. Flack. My name is John 22 Davis. I will be taking your deposition today. Let's 23 just start with a couple of simple items.</p> <p>24 Can you give your current work and home</p>	<p>Page 10</p> <p>1 A. Yes. Yes, medical malpractice. 2 Q. And that was -- all of those four to five 3 instances would have been in that context? 4 A. All four to five instances would have been 5 medical malpractice. 6 Q. Okay. Have you ever been involved as a 7 party in any litigation before? 8 A. (Indicating.) 9 Q. Is that a no? 10 A. No. 11 Q. Okay. Just -- just for the record, so 12 that the transcript is clear and the record is clear, 13 it -- I just ask that -- that you provide a verbal 14 answer of -- of yes or no. "Um-hums" or -- or just 15 kind of shaking your head, that -- that's going to be 16 hard for the court reporter to take down. 17 So the answer was no, that you have not 18 been involved as a party in any litigation before? 19 A. No. 20 Q. Okay. Have you ever been served a 21 subpoena or been a witness in any litigation? 22 A. No, I haven't. 23 Q. Okay. Let's start with -- I'm going to 24 mark an exhibit, which is the responses to the notice</p>
<p>1 addresses for me?</p> <p>2 A. My current work address is 7 Illinois 3 University, 701 North First Street in Springfield, 4 Illinois. My home address is 4420 Foxhall Lane in 5 Springfield, Illinois 62711.</p> <p>6 Q. Great. Thank you.</p> <p>7 Have you ever given testimony under oath 8 before, Dr. Flack?</p> <p>9 A. Yes. Yes, I have.</p> <p>10 Q. About how many times?</p> <p>11 A. Four to five.</p> <p>12 Q. Okay. What context would those occasions 13 have occurred in?</p> <p>14 A. Expert witness, being an expert witness in 15 cases.</p> <p>16 Q. Okay. For -- for all four or five of 17 those instances, that would have been testifying as an 18 expert witness similar to what you are doing today?</p> <p>19 A. Testifying as an expert witness in a case, 20 a specific case of medical care.</p> <p>21 Q. Like a medical malpractice case?</p> <p>22 A. Correct.</p> <p>23 Q. Sorry. I didn't catch your answer there, 24 is that a yes?</p>	<p>Page 11</p> <p>1 of this deposition.</p> <p>2 MR. DAVIS: For the record, I'm going to mark 3 these as PL-Flack as the beginning modifier. So this 4 will be Plaintiff-Flack 1.</p> <p>5 And then I will share my screen. Unless, 6 Steve, do you have a copy of the responses to the 7 notice? I can share my screen otherwise.</p> <p>8 MR. FOWLER: Yeah, I believe we do. Bear -- 9 bear with me.</p> <p>10 MR. DAVIS: Okay.</p> <p>11 MR. FOWLER: You know what, I'm --</p> <p>12 MR. DAVIS: That's fine, I'll just share my 13 screen.</p> <p>14 (WHEREUPON, a certain document was 15 marked Plaintiff-Flack Deposition 16 Exhibit No. 1, for identification, as 17 of 09/28/2021.)</p> <p>18 BY MR. DAVIS:</p> <p>19 Q. Dr. Flack, are you able to see the -- the 20 document I've shared?</p> <p>21 A. I can see it.</p> <p>22 Q. Okay. Did you personally review the 23 notice that we served on you when it was served?</p> <p>24 A. I've seen it, correct.</p>

<p>1 Q. Okay. Did you assist in the collection of 2 any documents that were produced to us responsive to 3 this notice?</p> <p>4 A. I did.</p> <p>5 Q. Can you describe to me, I guess, just at a 6 high -- we'll start at a high level, what type of 7 searches you did for responsive documents?</p> <p>8 A. Well, documents were some sent to me, some 9 I pulled off of expert witness reports, and others 10 came off of either reviewing the bibliography in 11 articles that were pulled, as well as searching for 12 valsartan NDMA on PubMed.</p> <p>13 Q. Okay. So let's -- that was a couple of 14 items there. I just want to make sure I got each one 15 down.</p> <p>16 So you said that some were sent to you. 17 Would that be by counsel?</p> <p>18 A. That would be by counsel.</p> <p>19 Q. Okay. Specifically who -- who of defense 20 counsel sent those to you?</p> <p>21 A. Offhand I don't remember.</p> <p>22 Q. Okay. And then you said that some you 23 pulled off of other expert witness reports?</p> <p>24 A. Yes, I did.</p>	<p>Page 14</p> <p>1 A. That's correct.</p> <p>2 Q. Okay. Any -- anything else that you did?</p> <p>3 A. No.</p> <p>4 Q. Okay. So I understand you to be talking 5 about documents that you searched for in preparing 6 your report, and we'll come back to that in a second.</p> <p>7 My -- my more specific question for right now, though, 8 was we had served as part of this notice that I'm 9 scrolling through certain document requests. You'll 10 see I've highlighted. There is about 11 of them. And 11 so some of the -- let's start with the ones that -- 12 that you appeared to -- to be refusing to produce 13 documents for.</p> <p>14 Was that your decision or did you come to 15 that decision after discussions with counsel?</p> <p>16 MR. FOWLER: Objection; form to the colloquy.</p> <p>17 Objection; form of the question.</p> <p>18 BY THE WITNESS:</p> <p>19 A. What documents are you talking about that 20 I refused to provide?</p> <p>21 BY MR. DAVIS:</p> <p>22 Q. Sure. I'll just -- I'll pull up an 23 example of one of these.</p> <p>24 So, for example -- so, for example, do you</p>
<p>Page 15</p> <p>1 Q. Would that be plaintiff expert witness 2 reports or defendant expert witness reports or both?</p> <p>3 A. On the plaintiff and defendant.</p> <p>4 Q. Okay. And then you said you reviewed the 5 bibliographies to some of the articles that you read 6 and tracked down information that way?</p> <p>7 A. That is correct.</p> <p>8 Q. Okay. And what were the final, I think 9 you had one or two final things?</p> <p>10 A. I searched valsartan and NDMA on the 11 PubMed site.</p> <p>12 Q. Okay. So when you say you searched 13 valsartan and NDMA, are you referring to those as 14 keywords?</p> <p>15 A. Yes.</p> <p>16 Q. Okay. So how was that -- how were those 17 keywords constructed? Was that, like, valsartan -- it 18 had to be valsartan and NDMA or did you search 19 valsartan and then you searched NDMA?</p> <p>20 A. When I do searches and I give you terms 21 like that, I use them both simultaneously.</p> <p>22 Q. Gotcha. So any -- any hits in that PubMed 23 database would have been hits for both valsartan and 24 NDMA?</p>	<p>Page 17</p> <p>1 see No. 6?</p> <p>2 A. Yes, I see it.</p> <p>3 Q. Okay. Do you understand that this is the 4 response that you've provided to that request that 5 I've highlighted?</p> <p>6 MR. FOWLER: Objection; form.</p> <p>7 BY THE WITNESS:</p> <p>8 A. I see it.</p> <p>9 BY MR. DAVIS:</p> <p>10 Q. Okay. Did you assist in preparing that 11 response?</p> <p>12 MR. FOWLER: Objection; form.</p> <p>13 BY MR. DAVIS:</p> <p>14 Q. You can answer the question, Dr. Flack.</p> <p>15 A. Any -- any document that concerns me I -- 16 I've had input on, and so, yes, I did.</p> <p>17 Q. Okay. And so do you understand that the 18 response, for example, to No. 6 here is a refusal to 19 provide responsive documents?</p> <p>20 MR. FOWLER: Objection; form.</p> <p>21 BY THE WITNESS:</p> <p>22 A. Actually, no, I -- I don't because 23 there -- there are no documents to produce.</p> <p>24 BY MR. DAVIS:</p>

<p>1 Q. So let's -- let's talk about what you did 2 to search for documents then that were responsive to 3 certain of these requests, and let me go through. 4 We'll start at the beginning then and just go through 5 each -- each of them. 6 So No. 1, do you understand that to be 7 asking for all of your invoices? 8 A. Yes, I do. 9 Q. Okay. And you have -- you have produced 10 one invoice in this as -- as a responsive document to 11 that request, correct? 12 A. No, that's incorrect. I've submitted two 13 invoices thus far. 14 Q. You've submitted two invoices to counsel? 15 A. Correct. 16 Q. Okay. Any reason why we would have only 17 been produced one? 18 A. Actually, it was later. 19 MR. DAVIS: Steve or Stephen, can I make a 20 request that that be sent to me as soon as possible so 21 that I can review it on a break? 22 MR. FOWLER: Sure, we'll run that down. I -- I 23 don't know that it wasn't provided, but we'll run down 24 the second invoice.</p>	<p>Page 18</p> <p>1 Q. There -- there are no written records of 2 that? 3 A. Nothing beyond a sticky on my computer 4 screen. 5 Q. Did you keep those stickies on your 6 computer screen? 7 A. No. 8 Q. Okay. So, for example, in the one invoice 9 we have that appears to log 43 and a half hours up 10 through, I believe, July 20th, when were you retained 11 in this case? 12 A. I don't remember the exact date I was 13 retained. It was well -- it was before then, but I 14 don't remember the exact date. 15 Q. Okay. So when you prepared that July 20th 16 invoice that logged 43 and a half hours, how did you 17 arrive at that number without going back to consult 18 any notes or anything like that? 19 MR. FOWLER: Objection; form, foundation. 20 BY THE WITNESS: 21 A. I think I've already answered that 22 question. 23 BY MR. DAVIS: 24 Q. And what was your answer to that question?</p> <p>Page 20</p>
<p>Page 19</p> <p>1 MR. DAVIS: Sure. I -- I can tell you I've only 2 got one invoice. The -- the folder that was produced 3 contained one document. 4 BY MR. DAVIS: 5 Q. Okay. Okay. So you've submitted two 6 invoices to counsel. 7 Is that your testimony? 8 A. That is correct. 9 Q. What about backup documents that you kept 10 to keep track of your time that went into those 11 invoices, do you keep written records of your -- the 12 time that you've spent and what you've done? 13 MR. FOWLER: Objection; form, foundation. 14 BY THE WITNESS: 15 A. My reported time on my invoices is 16 accurate. 17 BY MR. DAVIS: 18 Q. Okay. Well, my question wasn't whether 19 the time was accurate. My -- my question was whether 20 you kept written records that logged your time 21 contemporaneously to actually spending that time. 22 Do you understand the question? 23 A. Yeah, I understand the question. There 24 are no written real records of that.</p>	<p>Page 19</p> <p>1 A. I'm not going to repeat it. 2 Q. Sir, I'm -- you -- you have to repeat the 3 question -- or you have to repeat your answer. I'm 4 sorry. You have to play by the rules. 5 A. I've already answered -- I've already 6 answered the question. I said it's beyond my memory 7 the only thing that I've ever used is stickies on my 8 computer screen. 9 Q. Okay. And so my question, which, you 10 know, you still haven't -- and this is not a repeated 11 question, so I'm expecting a new answer here, is when 12 you wrote down 43 and a half hours as of July 20th, 13 how did you come up or tabulate those 43 and a half 14 hours? 15 MR. FOWLER: Objection; form. Asked and 16 answered, Counsel. 17 BY THE WITNESS: 18 A. I don't think there is any magic about how 19 you -- you tabulate it. You remember the time you 20 spent talking with counsel, you remember the time that 21 you spent on -- on documents. It wasn't extensive. 22 And there was no need for an extensive set of 23 documentation. And, actually, I believe 43 and a half 24 hours is -- I don't know. Is -- are you sure that</p> <p>Page 21</p>

<p style="text-align: right;">Page 22</p> <p>1 that only includes through -- through July and not 2 beyond that?</p> <p>3 BY MR. DAVIS:</p> <p>4 Q. Well, why don't we go ahead and mark that 5 as an exhibit. I'm marking Plaintiff-Flack 2, which 6 I'll open.</p> <p>7 (WHEREUPON, a certain document was 8 marked Plaintiff-Flack Deposition 9 Exhibit No. 2, for identification, as 10 of 09/28/2021.)</p> <p>11 BY MR. DAVIS:</p> <p>12 Q. Can you see that, Dr. Flack?</p> <p>13 A. Yes.</p> <p>14 Q. Do you recognize this as an invoice that 15 includes a date of service through July 20, 2021?</p> <p>16 A. I do.</p> <p>17 Q. Okay. And can you give me an estimate of 18 when you started working on this case?</p> <p>19 A. I ended up starting working on this case 20 sometime over the summer, because I had other -- other 21 projects, so sometime probably after June 1st.</p> <p>22 Q. But in the month of June?</p> <p>23 A. In the month of June, July. Uh-huh.</p> <p>24 Q. Okay. Well, is it June or July?</p>	<p style="text-align: right;">Page 24</p> <p>1 MR. FOWLER: Asked and answered.</p> <p>2 BY THE WITNESS:</p> <p>3 A. Again, I will repeat my answer to that. I 4 do not have the stickies.</p> <p>5 BY MR. DAVIS:</p> <p>6 Q. Okay. And so your -- your testimony is 7 that you went back through in your head about a month 8 and a half worth of work comprising 43 and a half 9 hours and accurately came up with that number?</p> <p>10 MR. FOWLER: Objection; form, mischaracterizing.</p> <p>11 BY THE WITNESS:</p> <p>12 A. Actually, that's not my testimony, and you 13 know it's not my testimony. My testimony is that I 14 had it in my head and I used computer stickies. I 15 didn't say I did either one solely.</p> <p>16 BY MR. DAVIS:</p> <p>17 Q. Okay. The second invoice that we don't 18 have, what's the -- what's the date of service on that 19 one?</p> <p>20 A. I don't remember. It was submitted a 21 couple of weeks ago and covered the interim period but 22 it was through the first part of September.</p> <p>23 Q. How many hours was that invoice for?</p> <p>24 A. My memory, let's see, around 12 hours</p>
<p style="text-align: right;">Page 23</p> <p>1 MR. FOWLER: Objection; form.</p> <p>2 BY THE WITNESS:</p> <p>3 A. I said I worked during the months of June 4 and July.</p> <p>5 BY MR. DAVIS:</p> <p>6 Q. Understood.</p> <p>7 So this July 20th invoice that is through 8 July 20th but dated July 21st would have encompassed 9 about a month and a half or a month and three weeks of 10 work roughly?</p> <p>11 A. Approximately, yes.</p> <p>12 Q. Okay. And so my -- my question is when 13 you wrote down 43 and a half hours, did you -- were 14 you going back to consult any written documents in 15 your possession to actually arrive at that number?</p> <p>16 MR. FOWLER: Objection; form, asked and 17 answered.</p> <p>18 BY THE WITNESS:</p> <p>19 A. I really answered that question now twice. 20 I told you that I had it in my head and I used 21 stickies on my computer screen.</p> <p>22 BY MR. DAVIS:</p> <p>23 Q. Okay. And do you still have those 24 stickies?</p>	<p style="text-align: right;">Page 25</p> <p>1 approximately.</p> <p>2 Q. Okay. We'll -- we'll come back to that 3 invoice. Let's keep going through Exhibit 1.</p> <p>4 MR. FOWLER: Counsel, we -- I have a hard copy 5 of that now which I can put before the witness if that 6 will -- if that will help you?</p> <p>7 MR. DAVIS: Sure, that would be great.</p> <p>8 BY MR. DAVIS:</p> <p>9 Q. Okay. In -- in light of that, Dr. Flack, 10 do you have that document in front of you, which is 11 Exhibit 1?</p> <p>12 A. I do.</p> <p>13 Q. Okay. I'm going to stop sharing my screen 14 then.</p> <p>15 Okay. No. 2, do you have that in front of 16 you, on Page 3?</p> <p>17 A. I do.</p> <p>18 Q. Okay. And that request is: "Copies of 19 any notes, i.e., written or electronic, reflecting 20 consulting or litigation work that has not been 21 documented in invoices."</p> <p>22 A. Yes.</p> <p>23 Q. Okay. And you -- your counsel produced 24 marked up copies of -- of two articles to us</p>

<p>1 yesterday.</p> <p>2 Are you familiar with what I'm talking 3 about?</p> <p>4 A. I'm familiar because I provided them to 5 counsel.</p> <p>6 Q. Okay. Those were the Pottegard and -- and 7 Gomm articles?</p> <p>8 A. Correct.</p> <p>9 Q. You have -- it appears that you have some 10 highlights and -- and written -- handwritten notes on 11 those articles.</p> <p>12 Is -- is that typically how you read? Are 13 you, I guess, an analog person, do you like to read 14 things printed out or do you like to read them 15 electronically?</p> <p>16 A. Actually, I'm a -- a pretty diverse 17 learner. I basically assimilate information in many 18 ways and I'm not wedded to any one in particular. 19 I've got a pretty good memory. Sometimes I highlight 20 things, but it just depends. If I'm reading from a 21 computer screen, I don't worry about it.</p> <p>22 Q. Were -- were those the only articles that 23 you printed out and marked up in that fashion?</p> <p>24 A. Yes. That's why you received them.</p>	<p>Page 26</p> <p>1 Q. Okay. And you can't remember in which 2 context you printed them, whether it was off the 3 e-mail from counsel or directly off the search on 4 PubMed?</p> <p>5 A. I'm not sure why you'd expect me to 6 remember something like that.</p> <p>7 Q. Well, you remember 43 and a half hours 8 pretty specifically, I thought you might remember 9 this.</p> <p>10 A. No, you're -- again, you're 11 mischaracterizing what I said. I said I used memory 12 and I used stickies on the computer screen. Okay. I 13 remember things that are relevant. Okay. And if you 14 can explain to me why this is relevant, perhaps I'll 15 feel bad about it, but --</p> <p>16 Q. Well, resp -- respectfully, Dr. Flack, I 17 don't have to explain the relevance of my questions, 18 and if I ask irrelevant questions that should be 19 perfectly fine with -- with your counsel since I'm 20 wasting my time, but I -- I'm entitled to an answer to 21 my question irrespective of your view of its 22 relevance.</p> <p>23 MR. FOWLER: Objection to form.</p> <p>24 BY THE WITNESS:</p>
<p>Page 27</p> <p>1 Q. Okay. Is that because those were the -- 2 and going back to what you told me before about the 3 sort of five to six ways that you collected documents 4 in this case, that last one was that you had searched 5 valsartan and NDMA in PubMed, were those the results 6 of that search?</p> <p>7 A. These articles have shown up in expert 8 witness expert reports, they have shown up on 9 searches, and they were provided by counsel. So you 10 can take your pick as to which way I got them.</p> <p>11 Q. Okay. But you're -- the answer to my 12 question is that, yes, those did come up in the 13 valsartan and NDMA search that you ran?</p> <p>14 A. Yes, they did.</p> <p>15 Q. And is that how you printed them, off that 16 search?</p> <p>17 A. I just printed them off a printer.</p> <p>18 Q. Well, what -- did you print them 19 contemporaneously to doing that search?</p> <p>20 A. Well, again, I'll try to answer this 21 question. These articles were sent to me by counsel, 22 I actually took them off of expert testimony that was 23 given or expert reports, and also PubMed. So they 24 could have come in any one of those forms.</p>	<p>Page 29</p> <p>1 A. Listen, again, I've answered questions for 2 you several times, and I -- if you want to waste my 3 time and your time, I'm glad to do it.</p> <p>4 BY MR. DAVIS:</p> <p>5 Q. Sure.</p> <p>6 So why did you print these two articles 7 and only these two articles?</p> <p>8 MR. FOWLER: Objection; form, foundation.</p> <p>9 BY THE WITNESS:</p> <p>10 A. There is no relevant reason to give you 11 for that, so I'm not going to offer you one.</p> <p>12 BY MR. DAVIS:</p> <p>13 Q. Well, again, I'm entitled to a -- an 14 answer regardless of your view of its relevance.</p> <p>15 So can you explain to me why you printed 16 those two articles and only those two articles?</p> <p>17 MR. FOWLER: Objection; form, foundation.</p> <p>18 BY THE WITNESS:</p> <p>19 A. I gave -- I gave you an answer.</p> <p>20 MR. FOWLER: Again, let me get my objection into 21 this.</p> <p>22 Lack of foundation, Counsel.</p> <p>23 BY MR. DAVIS:</p> <p>24 Q. Okay. Dr. Flack, can you answer the</p>

<p>1 question why you printed only those two articles?</p> <p>2 MR. FOWLER: Objection; form, mischaracterizing,</p> <p>3 lack of foundation.</p> <p>4 BY THE WITNESS:</p> <p>5 A. I've already given you my answer. There</p> <p>6 is no particular reason.</p> <p>7 BY MR. DAVIS:</p> <p>8 Q. Okay. Thank you.</p> <p>9 And there is nothing other -- no other</p> <p>10 documents that you found as part of your searches to</p> <p>11 these document requests that were responsive to Item</p> <p>12 No. 2?</p> <p>13 A. I've given all -- anything that I found to</p> <p>14 counsel and counsel has forwarded those to you.</p> <p>15 Q. Okay. And how did you -- in -- in</p> <p>16 searching for responsive documents to these requests,</p> <p>17 what did you do? Did you go -- did you have I file on</p> <p>18 this case, like a physical file that you looked in, do</p> <p>19 you have a file on a hard drive somewhere? Can you</p> <p>20 describe to me what you did to search for responsive</p> <p>21 documents to these requests?</p> <p>22 A. Well, some of it is by memory. There --</p> <p>23 there are things that I was asked for that don't</p> <p>24 exist, and so that was fairly straightforward. The</p>	<p>Page 30</p> <p>1 physical file, which it appears you do since you have</p> <p>2 two marked up copies that were produced to me, did you</p> <p>3 search that physical file in its entirety for</p> <p>4 responsive documents to this notice?</p> <p>5 MR. FOWLER: Objection to the colloquy.</p> <p>6 Go ahead.</p> <p>7 BY THE WITNESS:</p> <p>8 A. You received what is in my physical file.</p> <p>9 BY MR. DAVIS:</p> <p>10 Q. So you -- the entirety of your physical</p> <p>11 file included those two articles?</p> <p>12 A. That is correct.</p> <p>13 Q. Okay. What about an electronic file, did</p> <p>14 you search that exhaustively?</p> <p>15 MR. FOWLER: Objection; form.</p> <p>16 BY THE WITNESS:</p> <p>17 A. The electronic data that I had was</p> <p>18 forwarded to you by counsel. So did I search it, no.</p> <p>19 It was just forwarded.</p> <p>20 BY MR. DAVIS:</p> <p>21 Q. Okay. But you -- so you are saying you</p> <p>22 did not search your electronic data?</p> <p>23 MR. FOWLER: Objection; form.</p> <p>24 BY THE WITNESS:</p>
<p>Page 31</p> <p>1 files that I had are basically communications that</p> <p>2 come to me from either downloading articles or -- or</p> <p>3 PDFs from the -- from counsel and all -- are articles</p> <p>4 that I pulled and those are referenced and have been</p> <p>5 provided to you.</p> <p>6 Q. Okay. And so it -- it sounds like you do</p> <p>7 have a file, whether it's physical or an electronic</p> <p>8 format somewhere on this case?</p> <p>9 MR. FOWLER: Objection; form.</p> <p>10 BY THE WITNESS:</p> <p>11 A. You have received what I have from my</p> <p>12 counsel -- from counsel.</p> <p>13 BY MR. DAVIS:</p> <p>14 Q. I understand that. I -- I'm not asking</p> <p>15 you to confirm that. Simply I'm asking whether you</p> <p>16 keep a physical or electronic file on this matter?</p> <p>17 A. You have been forwarded physical data and</p> <p>18 electronic data that I have.</p> <p>19 Q. Okay. Okay. And do you -- your testimony</p> <p>20 is that you searched the sources where that data came</p> <p>21 from fully, is that correct?</p> <p>22 A. I don't understand the question.</p> <p>23 Q. Sure.</p> <p>24 Did you -- did you -- if you have a</p>	<p>Page 33</p> <p>1 A. My understanding of your question is did</p> <p>2 you get all of the information electronic and hard</p> <p>3 copy and you did.</p> <p>4 BY MR. DAVIS:</p> <p>5 Q. How can you be sure of that if you did not</p> <p>6 search any electronic file on your computer?</p> <p>7 MR. FOWLER: Objection; form, argumentative.</p> <p>8 BY THE WITNESS:</p> <p>9 A. So, searching a file and then sending you</p> <p>10 part of it is not going to assure you got all of it.</p> <p>11 The only thing I did was forwarded what I had, and it</p> <p>12 was forwarded to you. So I don't -- there is no</p> <p>13 problem with you getting everything because I didn't</p> <p>14 search it.</p> <p>15 BY MR. DAVIS:</p> <p>16 Q. So your testimony is that you did search</p> <p>17 your electronic media for items that would be</p> <p>18 responsive to this notice?</p> <p>19 MR. FOWLER: Objection; form. This has been</p> <p>20 asked and answered I think we've -- three times now.</p> <p>21 BY THE WITNESS:</p> <p>22 A. What I did was I forwarded the items that</p> <p>23 were requested that I had electronically and I just</p> <p>24 sent them en masse.</p>

<p>1 BY MR. DAVIS:</p> <p>2 Q. Okay. But it sounds like there were items 3 that were requested of you that you forwarded to 4 counsel to be produced.</p> <p>5 My -- my question is whether there were 6 items that were not requested that you may have found 7 had you searched your computer.</p> <p>8 Do you -- do you understand the 9 distinction there?</p> <p>10 A. I don't.</p> <p>11 MR. FOWLER: Objection to the form.</p> <p>12 BY THE WITNESS:</p> <p>13 A. There are no other relevant documents to 14 this consultation that I'm doing that I have that you 15 don't have.</p> <p>16 BY MR. DAVIS:</p> <p>17 Q. Okay. Let's look at No. 3: "Copies of 18 any notes or other documentation, including 19 PowerPoints, for any presentations, seminars or 20 classes given by Dr. Flack with regard to the risks 21 and benefits of" ARBs "or nitrosamines."</p> <p>22 Do you see that?</p> <p>23 A. I see that.</p> <p>24 Q. Okay. And it appears that we didn't</p>	<p>Page 34</p> <p>1 BY THE WITNESS:</p> <p>2 A. I'm not aware of any classes where they've 3 been discussed.</p> <p>4 BY MR. DAVIS:</p> <p>5 Q. Okay. Moving to No. 4, that one reads: 6 "Copies of any documents or articles relied upon for 7 the opinions set forth in the report served, if not 8 listed in the report."</p> <p>9 Do you see that?</p> <p>10 A. I see it.</p> <p>11 Q. Are there any such documents or articles 12 that you relied upon that you don't list somewhere in 13 your report?</p> <p>14 A. I have forwarded to you everything that 15 I've relied upon.</p> <p>16 Q. Okay. So there is no category of 17 documents out there that's -- that you've relied upon 18 that's not listed somewhere in your report?</p> <p>19 MR. FOWLER: Objection; form.</p> <p>20 BY THE WITNESS:</p> <p>21 A. I've forwarded to you the documents that 22 I've used in generating this report.</p> <p>23 BY MR. DAVIS:</p> <p>24 Q. I don't see the -- why you need to qualify</p>
<p>1 receive any documents responsive to this request.</p> <p>2 Is that a correct characterization?</p> <p>3 MR. FOWLER: Objection; form. Counsel, you do 4 have the objections that -- that clearly state 5 counsel's position that there are no responsive 6 documents because it's beyond the scope of Rule 26.</p> <p>7 So you have our objection and -- and understanding why 8 you have no such documents.</p> <p>9 BY MR. DAVIS:</p> <p>10 Q. Is that counsel's position, Dr. Flack, or 11 is that a position that you agree with?</p> <p>12 MR. FOWLER: Objection; form.</p> <p>13 BY THE WITNESS:</p> <p>14 A. My counsel and I are in sync on this. So 15 I have no problems with my counsel's position.</p> <p>16 BY MR. DAVIS:</p> <p>17 Q. Okay. Have you given any presentations, 18 seminars or classes on nitrosamines?</p> <p>19 A. I have never given a specific class on 20 nitrosamines, no.</p> <p>21 Q. Okay. Have you ever given any -- any 22 class on anything where nitro -- you recall 23 nitrosamines being a topic of -- of discussion?</p> <p>24 MR. FOWLER: Objection; form.</p>	<p>Page 35</p> <p>1 your answer like that. It's pretty simple question.</p> <p>2 My -- my question is: Are there any 3 documents out there that -- that you've relied upon 4 that are not somewhere in your report?</p> <p>5 MR. FOWLER: Objection to the colloquy.</p> <p>6 BY THE WITNESS:</p> <p>7 A. I am not qualifying it. I'm just telling 8 you that I have forwarded all of the documents to you 9 that I have used in my report. It is pretty 10 straightforward.</p> <p>11 BY MR. DAVIS:</p> <p>12 Q. So the answer is -- is no then, there are 13 no documents out there that you've relied upon that 14 are not somewhere in your report?</p> <p>15 MR. FOWLER: Objection to the form and you have 16 the objection to that request, Counsel.</p> <p>17 BY THE WITNESS:</p> <p>18 A. I've answered your question, and I'll 19 repeat that I have forwarded all of documents to you 20 through my counsel that have been used in the 21 generation of my expert report.</p> <p>22 BY MR. DAVIS:</p> <p>23 Q. Okay. Do you take any issue with me 24 interpreting that as no, there are no other documents</p>

<p>1 out there, because I'm happy to move on if that's what 2 you are trying to tell me?</p> <p>3 A. I can't really speak for how you can 4 interpret it. My answer is really clear, and 5 certainly no other documents being out there is 6 compatible with my answer.</p> <p>7 Q. Okay. Well, I'll take that as a no then 8 and we'll move on.</p> <p>9 MR. FOWLER: Object to the colloquy.</p> <p>10 BY MR. DAVIS:</p> <p>11 Q. Is your answer the same with No. 5, which 12 is: "Copies of any documents or articles reviewed in 13 connection with the report served, whether or not 14 listed in the report or attachments thereto"?</p> <p>15 MR. FOWLER: Same objection to the form.</p> <p>16 BY THE WITNESS:</p> <p>17 A. My answer to you is exactly the same.</p> <p>18 BY MR. DAVIS:</p> <p>19 Q. Thank you.</p> <p>20 No. 6 requests: "Any illustrations, 21 PowerPoints, images, charts, tables, or demonstrative 22 exhibits that may be used by you in connection with a 23 Daubert hearing or trial testimony in this 24 litigation."</p>	<p>Page 38</p> <p>1 MR. DAVIS: Well, I'm not -- I'm -- I'm asking a 2 question that's related to No. 6, which is whether he 3 is aware of the existence of any illustrations, 4 PowerPoints, images, charts, tables or demonstrative 5 exhibits that relate in any way to your report or its 6 exhibits that are not included in the -- in the report 7 or exhibits.</p> <p>8 BY MR. DAVIS:</p> <p>9 Q. Do you follow the question, Dr. Flack?</p> <p>10 MR. FOWLER: And I object. To be clear, don't 11 couch it as No. 6 if you are going past that.</p> <p>12 MR. DAVIS: It's related to No. 6. You can stop 13 the -- I'm asking a question of Dr. Flack.</p> <p>14 BY MR. DAVIS:</p> <p>15 Q. Dr. Flack, let me start over just so it's 16 clear.</p> <p>17 Are you aware of the existence, current 18 existence of any illustrations, PowerPoints, images, 19 charts, tables or demonstrative exhibits that relate 20 in any way to your report or its attachments that are 21 not included in the report or attachments that were 22 served on us?</p> <p>23 A. I have no such documents.</p> <p>24 Q. Okay. Thank you.</p>
<p>1 Do you see that?</p> <p>2 A. Yes, I see it.</p> <p>3 Q. Okay. And I understand that your counsel 4 has objected to responding to this request.</p> <p>5 Is that your understanding as well?</p> <p>6 A. That's what it says.</p> <p>7 Q. That's a yes?</p> <p>8 A. Yes.</p> <p>9 Q. Are you aware of the existence of any 10 illustrations, PowerPoints, images, charts, tables or 11 demonstrative exhibits that have not been included in 12 your report or its attachments?</p> <p>13 MR. FOWLER: Objection to form.</p> <p>14 BY THE WITNESS:</p> <p>15 A. There is nothing that's consistent with 16 this question that you haven't received.</p> <p>17 BY MR. DAVIS:</p> <p>18 Q. So the answer is, no, you are not aware of 19 the existence, current existence of any of those 20 categories of documents that do not appear in your 21 report or its exhibits?</p> <p>22 MR. FOWLER: Objection; form. Counsel, if you 23 are speaking of No. 6, you have now gone past that, so 24 object to the form of the question.</p>	<p>Page 39</p> <p>1 No. 7 is documentations of -- or 2 documentation of any research grants that you've been 3 provided to study any ARBs, nitrosamines, or health 4 effects potentially related thereto.</p> <p>5 Do you see that?</p> <p>6 A. Yeah.</p> <p>7 Q. Okay. And -- and we'll get to your CV in 8 a little bit where you do document research grants 9 related in some cases to ARBs. Let me focus on 10 nitrosamines.</p> <p>11 Have you received any research grant to 12 study nitrosamines ever?</p> <p>13 A. All research grants are listed in my CV.</p> <p>14 I've never received a grant to study nitrosamines.</p> <p>15 Q. Okay. Thank you.</p> <p>16 Have you ever received a research grant to 17 study cancer?</p> <p>18 A. I am not a cancer researcher and I've 19 never received a research grant to study cancer.</p> <p>20 Q. No. 8 is a slightly different request, but 21 is your answer the same with regard to research that 22 you've performed? Have you performed any research 23 regarding nitrosamines, for example?</p> <p>24 A. I have never done any of this with</p>

<p>1 nitrosamines, no.</p> <p>2 Q. Okay. And same answer with respect to 3 cancer?</p> <p>4 A. That would be correct.</p> <p>5 Q. Are you aware of any -- well, let me start 6 with -- so No. 9, it appears your counsel has objected 7 to producing those documents.</p> <p>8 Is that your understanding?</p> <p>9 A. So when I -- when I read No. 9 it's hard 10 to produce something that you are not aware that 11 exists. I'm not aware that there has been any of 12 these kinds of documents put forth in -- in my 13 practice, certainly not in my department, and so there 14 is really nothing there to produce.</p> <p>15 Q. Okay. Thank you. That answers my next 16 question, so I can move on.</p> <p>17 No. 10 is: "Any documents or 18 communications that" you have "received from any 19 person or entity with regard to nitrosamine impurities 20 in ARBs or any other drug."</p> <p>21 And it appears again your counsel, again, 22 has objected to providing documents responsive to this 23 request.</p> <p>24 Is that your understanding?</p>	<p>Page 42</p> <p>1 those communications exist they would be privileged?</p> <p>2 A. My -- if I have a -- a conversation about 3 a health-related matter with a patient, I am not at 4 liberty to discuss that with anybody else outside of 5 my care team or other people who are involved in their 6 care. I've had conversations here, but there is, 7 again, nothing to document.</p> <p>8 Q. Okay. And then, finally, No. 12 is 9 textbooks referenced by you in forming your opinions.</p> <p>10 Would any textbooks, references, or sites 11 be -- have been included in your report or its 12 attachments?</p> <p>13 A. I included everything that I used and 14 documented. I documented no textbook references in 15 the list of references that were included in my expert 16 report.</p> <p>17 Q. Okay. What's your understanding of who 18 has retained you in this matter? Is it just Teva or 19 have all of the manufacturer defendants in this 20 litigation retained you?</p> <p>21 MR. FOWLER: Objection.</p> <p>22 MS. KAPKE: Object to form.</p> <p>23 BY THE WITNESS:</p> <p>24 A. I was retained by Teva. I have no clear</p>
<p>Page 43</p> <p>1 A. My understanding of this is you are asking 2 me, for example, if I had a -- a person ask about 3 these impurities or if I sent a letter in regards to 4 that.</p> <p>5 No. 1, I don't have to give you privileged 6 information in the sense of things that are specific 7 to a patient because we don't release information 8 specific to patients to outside entities.</p> <p>9 No. 2, I don't have any written documents 10 that I've had conversations with people in person and 11 over the phone about this and all, but there is 12 nothing to produce in regards to that.</p> <p>13 Q. Okay. Well, let -- let's take it 14 stepwise, because No. 10 is documents that you've 15 received, not ones that you've sent.</p> <p>16 So have -- are you aware of having 17 received documents regarding nitrosamine impurities 18 in -- in any ARB or other drug from any entity or 19 person?</p> <p>20 A. No, I am not.</p> <p>21 Q. Okay. And then No. 11, I believe you 22 touched on this, this is communications or documents 23 to anyone regarding nitrosamine impurities.</p> <p>24 And is your answer that to the extent</p>	<p>Page 45</p> <p>1 understanding about other defendants, and I've -- I've 2 never -- never focused on that. So my understanding 3 that I was retained by Teva and -- and all, but there 4 may be others involved.</p> <p>5 BY MR. DAVIS:</p> <p>6 Q. Okay. Have you -- in -- in preparing your 7 report or preparing for your testimony today, have you 8 talked with counsel for any of the other defendants?</p> <p>9 MR. FOWLER: Objection; form.</p> <p>10 BY THE WITNESS:</p> <p>11 A. What -- what are you -- what are you 12 asking me? I mean, have I talked to --</p> <p>13 BY MR. DAVIS:</p> <p>14 Q. Sure. My -- well, let me -- let me 15 rephrase it in a more particularized way, which is:</p> <p>16 In your work on this matter, have you had 17 communications only with Teva attorneys at Greenberg 18 Traurig or have you had any communications of any kind 19 with counsel for the other defendants?</p> <p>20 MR. FOWLER: Objection; form.</p> <p>21 BY THE WITNESS:</p> <p>22 A. My conversations on this have been with 23 Teva. There have been other counsel there, but I 24 speak with Teva.</p>

<p>1 BY MR. DAVIS:</p> <p>2 Q. Okay. Have you ever had any 3 communications with counsel for any of the other 4 defendants that occurred outside of the presence of 5 counsel for Teva?</p> <p>6 MR. FOWLER: Objection; form.</p> <p>7 BY THE WITNESS:</p> <p>8 A. I've never had any communication with any 9 counsel outside of conversations or things that have 10 occurred with Teva being there, Greenberg Traurig.</p> <p>11 BY MR. DAVIS:</p> <p>12 Q. Okay. And that includes written 13 communications like e-mails?</p> <p>14 A. It really includes anything, everything.</p> <p>15 Q. Okay. Have you spoken with any other 16 experts retained by the defense in this litigation?</p> <p>17 A. I have not spoken with any other experts 18 retained.</p> <p>19 Q. How about written communications, like 20 e-mails?</p> <p>21 A. I have not communicated in any form with 22 any other experts in this case.</p> <p>23 Q. Okay. You did review a number of expert 24 reports on -- on both sides, correct?</p>	<p>Page 46</p> <p>1 all opinions the witness will express and the basis 2 and reasons for them.</p> <p>3 Do you feel your report complies with 4 that?</p> <p>5 MR. FOWLER: Objection to form.</p> <p>6 BY THE WITNESS:</p> <p>7 A. My report complies with that statement up 8 to the time that I -- I wrote the report. We don't 9 stop learning and assimilating information and 10 acquiring information at any one particular date. So 11 my report up to the date I wrote that report is in 12 compliance with that.</p> <p>13 BY MR. DAVIS:</p> <p>14 Q. Okay. And so it con -- it contains a 15 complete statement of all of your opinions and the 16 basis and reasons for them as of the date you signed 17 it?</p> <p>18 A. My report complies with the Federal 19 article you -- you mentioned, No. -- No. 26, as of the 20 date that it was completed.</p> <p>21 Q. And to be clear, you haven't served any 22 kind of updated, revised report since that date, 23 correct?</p> <p>24 A. I have not served any updated, revised</p>
<p>1 A. I've reviewed some of the expert reports, 2 correct.</p> <p>3 Q. Okay. Which of the defendants' expert 4 reports have you reviewed?</p> <p>5 A. I don't remember offhand. It has been a 6 while, so I don't know exactly which ones I reviewed.</p> <p>7 Q. Okay. Are you relying on any of the 8 opinions expressed by any of these other defense 9 experts in forming your own opinions?</p> <p>10 A. My opinion is expressed in my expert 11 report and the way my testimony goes today is based 12 on -- on my understanding and interpretation of -- of 13 data and not re -- really relying on -- on other 14 expert witness reports to guide me in any way.</p> <p>15 Q. In preparing your report, did you 16 familiarize yourself with Federal Rule of Civil 17 Procedure 26, which governs the scope and contents of 18 your report?</p> <p>19 A. No, I mean, I did not familiarize my -- 20 myself with that.</p> <p>21 Q. Okay. Do you feel that your report 22 complies with Rule 26(a)(2)(B)(1), and I'll phrase 23 exactly what I'm talking about here, which requires 24 that the report must contain a complete statement of</p>	<p>Page 47</p> <p>1 report since that date, no.</p> <p>2 Q. Let's go ahead and mark it. I'm marking 3 your report as Plaintiff-Flack 3.</p> <p>4 (WHEREUPON, a certain document was 5 marked Plaintiff-Flack Deposition 6 Exhibit No. 3, for identification, as 7 of 09/28/2021.)</p> <p>8 BY MR. DAVIS:</p> <p>9 Q. I assume you have a copy of your report 10 printed out, Dr. Flack?</p> <p>11 A. Yes, I do.</p> <p>12 Q. Okay. Do you recognize this as your 13 report which you appear to have signed August 2nd, 14 2021?</p> <p>15 A. I recognize this as the report I signed, 16 correct.</p> <p>17 Q. Okay. When did you start actually writing 18 this report?</p> <p>19 A. Well, I previously stated that I started 20 working on this during the month of June, in early 21 June, and so my work started then and was completed by 22 the date on my report.</p> <p>23 Q. Okay. But -- and that date is August 2nd?</p> <p>24 A. That's what the report says, yes.</p>

<p>1 Q. Let me refer you back to your invoice for 2 a second, the -- the first one that we have. 3 Do you see that, Dr. Flack? 4 A. I see it. 5 Q. Do you see the description of services for 6 those 43 and a half hours? 7 A. Yeah. 8 Q. Okay. It's -- it reads: 9 "Conduct research and review documents and 10 materials, prepare for and participate in meeting, 11 participate in telephone meeting." 12 Do you see that? 13 A. I see it. 14 Q. Okay. Is it -- am I to take that to mean 15 that you had not started writing your report as of 16 July 20th? 17 A. No, you are not to take it as that because 18 that's not the case. 19 Q. Okay. So even though it's not listed in 20 your description of services, you were, in fact, 21 writing your report prior to July 20th? 22 A. I was writing my report starting in June 23 of this past year. 24 Q. Okay. And while we have it up, as of</p>	<p>Page 50</p> <p>1 BY MR. DAVIS: 2 Q. Sorry. The conclusion that what was 3 erroneous? 4 A. The conclusion that I only gave 5 conclusions is erroneous. There is plenty of 6 rationale for why I came to the conclusions that I 7 did. 8 Q. Okay. Let's start at -- with just the 9 very first page of your report. 10 You -- you state in that first paragraph 11 that: "...each of my opinions is based on the 12 materials I have reviewed in connection with this 13 litigation, the methods and procedures of science, and 14 my knowledge of recognized medical and scientific 15 principles..." 16 And I'll continue: "Each opinion is 17 offered to articulate a sufficiently reliable basis 18 for my opinions concerning this case." 19 Do you see that? 20 A. I see it. 21 Q. Okay. And by "opinions" there, you mean 22 the opinions that are expressed in your report, 23 correct? 24 A. I'm talking about the opinions in my</p>
<p>Page 51</p> <p>1 July 20th, you had billed \$26,100 at a rate of \$600 2 per hour? 3 A. That would be correct. 4 Q. So when you signed your report on 5 August 2nd, did you feel that you had, in fact, 6 accomplished your assignment of setting forth your 7 opinions in compliance with Rule 26 as I read it? 8 MR. FOWLER: Objection; form. 9 BY THE WITNESS: 10 A. I had felt I had accomplished writing a 11 comprehensive report that was within the scope of what 12 I was asked to do. 13 BY MR. DAVIS: 14 Q. Okay. Did you endeavor just to list your 15 conclusions in the report or also to explain the 16 process by which you arrived at those conclusions? 17 MR. FOWLER: Objection; form. The report speaks 18 for itself. 19 BY THE WITNESS: 20 A. So my answer to that is that really the -- 21 it is pretty self-evident in there that, one, I not 22 only gave conclusions but I gave actual factual data 23 and interpretations that led to those conclusions. So 24 the premise that I only gave conclusions is erroneous.</p>	<p>Page 53</p> <p>1 report. 2 Q. And in coming to those opinions, did you 3 endeavor to discuss the facts and reference materials 4 that you found to be most important to you in coming 5 to those opinions? 6 A. Yes, I did. 7 Q. Do you feel like you wrote your report 8 carefully and with precision? 9 A. Anything that I write and put my name on I 10 write carefully with precision and care. 11 Q. And that includes the actual wording of 12 the report as well as the substantive content? 13 MR. FOWLER: Objection; form. 14 BY THE WITNESS: 15 A. That includes all of that. 16 BY MR. DAVIS: 17 Q. Did you give your report a detailed once 18 over or twice over before actually signing it when it 19 came time to sign? 20 A. By the time I write a report I read it and 21 worked on it many times more than a once or twice 22 over. So at the very end, you know, at some point you 23 finish it, abandon that, but there as been many 24 iterations that you -- you go through and you look at</p>

<p>1 it and so there is -- there is ongoing scrutiny. So 2 it's not just a I write, write, write and then once or 3 twice at the end I look at it.</p> <p>4 Q. Well, sure, I guess my -- my question is 5 more geared towards prior to signing it, did you give 6 it a thorough review to make sure that you had not 7 missed anything important?</p> <p>8 MR. FOWLER: Objection; form.</p> <p>9 BY THE WITNESS:</p> <p>10 A. So -- so anything that I write, including 11 this report, I'm very careful about what I write, what 12 my interpretations are, how I write it, and -- and all 13 in this report, again, is no exception to that.</p> <p>14 BY MR. DAVIS:</p> <p>15 Q. Okay. For example, in -- in that review 16 process, did you check your references for accuracy as 17 much as possible?</p> <p>18 A. You always check your references for 19 accuracy, correct.</p> <p>20 Q. Okay. And that you didn't leave out any 21 important reference?</p> <p>22 A. I don't know what you consider an 23 important reference. I used references that I thought 24 were -- were important. Somebody else might think</p>	<p>1 there are quite a few documents or even categories of 2 documents listed in that Exhibit B that are not in 3 your report, and I'll give an example, like the -- you 4 reference a number of plaintiff bellwether documents 5 for bellwether plaintiffs and their records in your 6 materials considered, but I don't see any reference to 7 that in -- in your report.</p> <p>8 Can you explain why that would be?</p> <p>9 MR. FOWLER: Object to the form of the question.</p> <p>10 BY THE WITNESS:</p> <p>11 A. First of all, when you are reviewing 12 documents, literature in writing, you don't -- you 13 don't reference everything that you read. You 14 reference the most important documents. And I 15 referenced the most important documents and anything 16 else that was available to me was disclosed to you, 17 but there -- there is no -- everybody who writes does 18 it differently, and -- and all and I -- I did it the 19 way that I am comfortable with doing it. I published 20 over 210 papers and I am an associate editor for a 21 journal and I know this process backwards and forwards 22 how to write and communicate.</p> <p>23 Q. Sure. And I'm not challenging you on 24 that. I'm just trying to understand what it means to</p>
<p>1 others are important. And so that is an unanswerable 2 question for anyone other than myself.</p> <p>3 Q. Well, sure, and that's what I was asking, 4 I guess. Let me rephrase it.</p> <p>5 Did you -- did you make sure that you did 6 not leave out any reference that you thought was 7 important in coming to your opinions as expressed in 8 the report?</p> <p>9 A. Up to the time that I wrote the report, I 10 included the references that I believed to be the 11 important references, and I've continued to work since 12 the report is -- is written as I should and am 13 supposed to. So that doesn't preclude the fact 14 that -- that I may find something else in the 15 literature that's not in the report, but it doesn't 16 invalidate what I did up to that point of August the 17 2nd.</p> <p>18 Q. Okay. Well, let me -- let me ask it a 19 slightly different way.</p> <p>20 You have an Exhibit B, a list of materials 21 considered, correct? Do you -- do you understand that 22 that's an attachment to your report, Dr. Flack?</p> <p>23 A. Yes.</p> <p>24 Q. Okay. And would you agree with me that</p>	<p>1 be -- to have made your list of materials considered. 2 Is that -- are all of those things just 3 things that you've reviewed and I think you -- as you 4 testified just were made available to you, is that how 5 I'm to understand that or does that not necessarily 6 factor into your opinions?</p> <p>7 MR. FOWLER: Hold on. Object to the colloquy, 8 object to the compound question. Can you ask a clear 9 question, Counsel? I'm not following.</p> <p>10 MR. DAVIS: Well, hold on, the witness hasn't 11 said it's not clear.</p> <p>12 BY MR. DAVIS:</p> <p>13 Q. Dr. Flack, did you understand my question?</p> <p>14 A. It's not clear.</p> <p>15 Q. Okay. So you -- you testified in a 16 previous answer that those -- that the materials 17 considered were documents that were made available to 18 you, right?</p> <p>19 A. I considered documents from a variety of 20 sources, including those that have been made available 21 to me, as previously described.</p> <p>22 Q. Okay. And -- and my -- my question is: 23 Are those -- did it make -- was it sufficient to make 24 that list simply that you reviewed the document or am</p>

<p>1 I to interpret every single one of those documents as 2 something that you relied upon in forming your 3 opinions?</p> <p>4 MR. FOWLER: Objection; form.</p> <p>5 BY THE WITNESS:</p> <p>6 A. Everything that was supplied to me did not 7 get extensively review. Some of it was cursorily 8 reviewed, some of it was not reviewed. You simply 9 have what was supplied to me.</p> <p>10 BY MR. DAVIS:</p> <p>11 Q. Okay. Thank you. I just am trying to get 12 an understanding there, and I think that clears it up.</p> <p>13 Before I move into your CV, we -- we've 14 been going for more than an hour. Should we take a 15 quick break? Do you want to take a break, Dr. Flack, 16 before I jump into another set of questions?</p> <p>17 A. Yeah, that's fine.</p> <p>18 MR. DAVIS: Okay. Let's go off the record.</p> <p>19 MR. FOWLER: Five, six minutes, Counsel?</p> <p>20 MR. DAVIS: Are we off the record?</p> <p>21 THE VIDEOGRAPHER: The time is 10:12 a m., off 22 the record.</p> <p>23 (WHEREUPON, a recess was had 24 from 10:12 to 10:24 a m.)</p>	<p>Page 58</p> <p>1 Exhibit No. 4, for identification, as 2 of 09/28/2021.)</p> <p>3 MR. FOWLER: And I've got a hard copy in front 4 of him, Counsel.</p> <p>5 MR. DAVIS: Thank you.</p> <p>6 BY MR. DAVIS:</p> <p>7 Q. Okay. Do you recognize this as your CV, 8 Dr. Flack?</p> <p>9 A. I recognize this as my CV.</p> <p>10 Q. Okay. When is the last time you updated 11 this CV as it was produced to us?</p> <p>12 A. It should be dated on the front. And it 13 was probably sometime in the summer, like spring or 14 summer.</p> <p>15 Q. Sure. I -- I see just above your 16 signature June 28th, 2021.</p> <p>17 A. That would be an approximate timeframe, 18 correct.</p> <p>19 Q. Okay. Was this CV prepared specifically 20 for -- for this expert report assignment or is this 21 the CV that you have maintained as part of your -- 22 your work outside of this -- this litigation?</p> <p>23 A. I maintain a CV that is almost never 24 tailored to any one specific request. This is just my</p>
<p>Page 59</p> <p>1 THE VIDEOGRAPHER: The time is 10:24 a m., on 2 the record.</p> <p>3 BY MR. DAVIS:</p> <p>4 Q. Okay. Dr. Flack, just a couple of cleanup 5 items before we move on.</p> <p>6 You -- you had testified earlier that you 7 had served as an expert witness in four to five 8 medical malpractice cases, is that right?</p> <p>9 A. That is correct.</p> <p>10 Q. Okay. Did any of those cases have 11 anything to do with any of the issues in this 12 litigation?</p> <p>13 A. None of the cases I previously served as 14 an expert witness had anything to do with this 15 litigation.</p> <p>16 Q. Okay. Or any of the issues around 17 nitrosamines and cancer, anything like that?</p> <p>18 A. None of the cases that I previously have 19 been an expert witness in had anything to do with this 20 litigation.</p> <p>21 Q. Okay. I'm going to mark your CV as 22 Exhibit 4.</p> <p>23 (WHEREUPON, a certain document was 24 marked Plaintiff-Flack Deposition</p>	<p>Page 60</p> <p>1 CV. It is as it is.</p> <p>2 Q. Okay. Did you make any changes to it for 3 use in this litigation?</p> <p>4 A. Did I make changes other than updating 5 things that may needed to be included, no.</p> <p>6 Q. Okay. Can you briefly walk me through 7 your -- we'll start with your educational background.</p> <p>8 Can you walk me through that in narrative 9 format, briefly?</p> <p>10 A. So I went to Chickasha High School, 11 subsequently went to Langston University where I was a 12 chemistry major, math minor, football player; entered 13 medical school at the University of Oklahoma in 1978, 14 graduated in '82; enrolled in an internal medicine 15 residency there '82 to '85; '85 to '86 I was the chief 16 resident in medicine there; '86 to '88 I was on 17 faculty; and then I left for the University of 18 Minnesota where I did, again, National Institutes of 19 Health postdoctoral fellowship, cardiovascular 20 epidemiology, and finished my MPH there and have been 21 a faculty member there and other places ever since.</p> <p>22 Q. Okay. Let's -- and let's discuss your 23 professional experience then.</p> <p>24 You -- you started -- where -- where is</p>

<p>1 the University of Minnesota located?</p> <p>2 A. Minneapolis.</p> <p>3 Q. Okay. Is that where you would say your</p> <p>4 post-academic career started?</p> <p>5 A. No. My post-academic career started at</p> <p>6 Oklahoma. I started working on my MPH at Oklahoma</p> <p>7 University College of Health. I spent two years doing</p> <p>8 that as an instructor in the Department of Medicine</p> <p>9 before I moved on to finish my MPH. I completed my</p> <p>10 MPH post-doc in cardiovascular epi at the University</p> <p>11 of Minnesota.</p> <p>12 Q. Okay. What -- what years were you in --</p> <p>13 in Oklahoma?</p> <p>14 A. I was in medical school through the end of</p> <p>15 my faculty there between 1978 and 1988.</p> <p>16 Q. Okay. And then what years were you in</p> <p>17 Minnesota?</p> <p>18 A. I was in Minnesota between '88 to probably</p> <p>19 '94, a total of about six years.</p> <p>20 Q. Okay. And then after University of</p> <p>21 Minnesota, where did you go?</p> <p>22 A. I switched my education by that time and I</p> <p>23 spent three years at Wake Forest Bowman Gray before I</p> <p>24 moved to Wayne State in Detroit.</p>	<p>Page 62</p> <p>1 medicine, I am also certified as a specialist in</p> <p>2 clinical hypertension by the now defunct American</p> <p>3 Society of Hypertension, which was folded into AHA,</p> <p>4 American Heart Association, and I am president of the</p> <p>5 American Hypertension Specialist Certification</p> <p>6 Program.</p> <p>7 Q. Okay. Do you have any board</p> <p>8 certifications in oncology or anything cancer related?</p> <p>9 A. I have no certifications in oncology</p> <p>10 because I've never had anything other than residency</p> <p>11 training in oncology.</p> <p>12 Q. Okay. How about, to the extent they</p> <p>13 exist, any board certifications in toxicology or</p> <p>14 anything related to exposure to hazardous chemicals?</p> <p>15 A. I am not board certified in toxicology.</p> <p>16 Q. None of your research interests outside of</p> <p>17 this litigation involve nitrosamines or cancer, do</p> <p>18 they?</p> <p>19 MR. FOWLER: Objection; form.</p> <p>20 BY THE WITNESS:</p> <p>21 A. I have not conducted any research in</p> <p>22 nitrosamines, no.</p> <p>23 BY MR. DAVIS:</p> <p>24 Q. Okay. Looking through your CV, is it fair</p>
<p>1 Q. Okay. At Wayne State in Detroit, what</p> <p>2 was -- what years were you in Detroit?</p> <p>3 A. 1997 to 2015.</p> <p>4 Q. And you were on the faculty at Wayne</p> <p>5 State?</p> <p>6 A. On the faculty at Wayne State.</p> <p>7 Q. Okay. Did you have a private practice as</p> <p>8 well?</p> <p>9 A. I had a practice, a clinical practice</p> <p>10 there the entire time I was there.</p> <p>11 Q. Okay. What was the name of your clinical</p> <p>12 practice?</p> <p>13 A. I was director of the hypertension clinic.</p> <p>14 Q. The hypertension clinic at -- at where?</p> <p>15 A. At Wayne State.</p> <p>16 Q. Oh, at Wayne State. Okay.</p> <p>17 And then since 2015 to today, you've --</p> <p>18 you've been in Springfield, Illinois, is that right,</p> <p>19 at SIU?</p> <p>20 A. I've been at Southern Illinois since May</p> <p>21 of 2015.</p> <p>22 Q. Do you have any board certifications?</p> <p>23 A. Certified -- board certified by the</p> <p>24 American Board of Internal Medicine in internal</p>	<p>Page 63</p> <p>1 to say that you've received a lot of funding over the</p> <p>2 years from pharmaceutical companies?</p> <p>3 MR. FOWLER: Objection; form.</p> <p>4 BY THE WITNESS:</p> <p>5 A. From my perspective, I had received</p> <p>6 funding from a -- a range of sources and from a range</p> <p>7 of pharmaceutical companies to conduct varied</p> <p>8 research.</p> <p>9 BY MR. DAVIS:</p> <p>10 Q. And well, let's -- let's break it up, I</p> <p>11 guess.</p> <p>12 Would you agree that you've received</p> <p>13 funding from pharmaceutical companies in the form of</p> <p>14 research grants?</p> <p>15 A. Well, that question is pretty clear from</p> <p>16 my CV. Absolutely I have.</p> <p>17 Q. Okay. How about consulting work, speaker</p> <p>18 programs, advisory boards, things like that?</p> <p>19 A. I've done some advisory boards. The</p> <p>20 speaker bureau, I'm not on any speakers bureaus at --</p> <p>21 at present. That's all no. And so, yeah, I've --</p> <p>22 I've consulted with companies on -- on various things</p> <p>23 related to their products and research they are doing.</p> <p>24 Q. Okay. You mentioned you are not on any</p>

<p>1 speakers bureaus at present.</p> <p>2 Were you in the past on speakers bureaus?</p> <p>3 A. Yes, I was on speakers bureaus in the</p> <p>4 past, but I -- I no longer do that.</p> <p>5 Q. Why don't you do that any longer?</p> <p>6 A. One, I don't really have time to do it</p> <p>7 because the pharmaceutical industry in certain areas</p> <p>8 has -- has, one, they have de-emphasized speakers</p> <p>9 bureaus and, two, they are -- they are promotional,</p> <p>10 and when I talk, I am not really interested in being</p> <p>11 promotional. So any talking that I do is typically</p> <p>12 done under organizations like the American Heart</p> <p>13 Association or -- or other organizations. Sometimes</p> <p>14 pharmaceuticals may sponsor certain things, but that's</p> <p>15 rare that I work directly with a pharmaceutical</p> <p>16 company at a speaking engagement.</p> <p>17 Q. Okay. Do you have any understanding of</p> <p>18 why pharmaceutical companies have de-emphasized</p> <p>19 speakers programs?</p> <p>20 MR. FOWLER: Objection; form, speculation.</p> <p>21 BY THE WITNESS:</p> <p>22 A. Yeah, I think everybody pretty much knows</p> <p>23 that the FDA cracked down the -- also, two, the</p> <p>24 individual practitioner is less of a control factor</p>	<p>Page 66</p> <p>1 A. I would guess that it was probably</p> <p>2 somewhere around 2008, 2010 when -- when I was no</p> <p>3 longer doing it.</p> <p>4 Q. Do you recall what year you started</p> <p>5 participating in speakers bureaus?</p> <p>6 A. I started in 1986 when I joined the</p> <p>7 faculty at the University of Oklahoma.</p> <p>8 Q. And to be clear, that's when you started</p> <p>9 participating in speakers bureaus for pharmaceutical</p> <p>10 companies?</p> <p>11 A. Correct.</p> <p>12 Q. Okay. And your testimony is that you</p> <p>13 still do consulting work for various pharmaceutical</p> <p>14 companies, is that right?</p> <p>15 A. I do for -- for pharmaceutical companies,</p> <p>16 device companies, I've done consulting related to --</p> <p>17 typically related to research that's ongoing.</p> <p>18 Q. Would you have also started that</p> <p>19 consulting work back in 1986 or was that a different</p> <p>20 start date?</p> <p>21 A. Well, the people who get called in for</p> <p>22 consulting are typically people who have an</p> <p>23 established track record and a clear footprint in --</p> <p>24 in the field. So it takes a while to do that. So a</p>
<p>Page 67</p> <p>1 and who writes what prescriptions now, a lot of that</p> <p>2 is controlled on what's on the formulary, decision is</p> <p>3 made oftentimes outside of the practitioner.</p> <p>4 So the approach that pharmaceutical</p> <p>5 companies have taken to actually promote their</p> <p>6 products has just morphed over time in an explainable</p> <p>7 way, understandable way.</p> <p>8 BY MR. DAVIS:</p> <p>9 Q. Okay. But you did mention that part of</p> <p>10 the reason for that de-emphasizing is because they got</p> <p>11 in a lot of trouble over it, right?</p> <p>12 MR. FOWLER: Objection; form, mischaracterizes</p> <p>13 the testimony.</p> <p>14 BY THE WITNESS:</p> <p>15 A. There are -- there are a variety of</p> <p>16 reasons, including the FDA crackdowns that really</p> <p>17 forced a change in how pharmaceutical companies</p> <p>18 sponsor lectures and give promotion and now the -- the</p> <p>19 issue of promotion is -- has been de-emphasized and</p> <p>20 it's really not something that I'm engaged in at -- at</p> <p>21 this point.</p> <p>22 BY MR. DAVIS:</p> <p>23 Q. About what year did you stop participating</p> <p>24 in speakers bureaus for pharmaceutical companies?</p>	<p>Page 69</p> <p>1 lot of the consulting probably did not start until</p> <p>2 sometime in -- in the 1990s because I needed time to</p> <p>3 really develop a footprint and a reputation in the</p> <p>4 field.</p> <p>5 Q. What about advisory boards?</p> <p>6 A. Yeah, I've done advisory boards from how</p> <p>7 to recruit into clinical research, I've done advisory</p> <p>8 boards where I've -- I've sat on mock FDA panels</p> <p>9 because I spent three years, I believe about three</p> <p>10 years as a standing member of the FDA cardiorenal</p> <p>11 advisory panel, and -- and also I've been on advisory</p> <p>12 boards where companies are taking their product to the</p> <p>13 FDA and they put together a mock FDA panel or a couple</p> <p>14 of them before they go and because of my experience</p> <p>15 I've served on those.</p> <p>16 Q. Okay. Do you currently still serve on</p> <p>17 pharmaceutical company advisory boards?</p> <p>18 A. So typically the advisory boards are ad</p> <p>19 hoc as opposed to standing, and so am I on any</p> <p>20 standing advisory boards at this moment, no.</p> <p>21 Q. When is the last ad hoc pharmaceutical</p> <p>22 company advisory board that you've participated in?</p> <p>23 A. I participated in an advisory board about</p> <p>24 two weeks ago with Amgen on their RISE program which</p>

<p>1 was looking at how to recruit African Americans into 2 their clinical research program so they had better 3 representation in their trials before they went to the 4 FDA for approval.</p> <p>5 Q. Okay. Did you receive any kind of 6 honorarium or payment for that advisory board that you 7 sat on for Amgen?</p> <p>8 A. You know my time is valuable and that I -- 9 I get paid when -- when I -- when I do this, and of 10 course I got paid to do it.</p> <p>11 Q. Okay. And that's the case for -- for all 12 of these categories of pharmaceutical 13 industry-supported items we went through, like 14 speakers bureaus, consulting, advisory boards, those 15 all come with -- with payment, correct?</p> <p>16 A. I am on an advisory board most of the time 17 I've been paid. There are a couple of times I 18 haven't, but it was typically a very young company and 19 I was just interested in what they were doing and 20 beyond expenses I didn't get payment.</p> <p>21 Q. Okay. Let's go to the grants and 22 contracts portion of your report around page -- it 23 starts at the bottom of Page 23. And let's start with 24 the active -- I see that you've broken it down by</p>	<p>Page 70</p> <p>1 Q. Okay. I've noticed that some of the 2 numbers across this Grants and -- and Research section 3 of your report have parentheses around them and some 4 don't.</p> <p>5 Is the parenthetical meant to signify 6 anything or is that just using parentheses sometimes 7 but not others?</p> <p>8 A. Well, it's not really meant to signify 9 anything except that was the estimate. Some of the 10 grants you -- you basically get paid for recruiting 11 participants, so you don't really know the work of the 12 grant until you've finished your recruitment, so it is 13 really harder to estimate. So a lot of times there 14 may not be a number there, occasionally there -- there 15 might be, but there -- there is no special meaning to 16 it.</p> <p>17 Q. Okay. Do you own or -- or partially own 18 an -- any entity?</p> <p>19 A. I'm not sure I understand your question. 20 What entity are you talking about?</p> <p>21 Q. Well, I'm asking if you are the owner or 22 partial owner of any business entity, LLP, LLC, 23 corporation?</p> <p>24 A. No, I'm not a part owner of anything</p>
<p>1 active, pending review, submitted but unfunded and 2 then completed.</p> <p>3 Do you see that, and that it extends 4 through about Page 34 of your report from Page 23?</p> <p>5 A. Yes.</p> <p>6 MR. FOWLER: You keep saying "report," Counsel. 7 CV.</p> <p>8 MR. DAVIS: Sorry. CV. My apologies.</p> <p>9 BY MR. DAVIS:</p> <p>10 Q. So let's start with the active ones. Can 11 you tell me what "FTE" means?</p> <p>12 A. Full-time equivalent.</p> <p>13 Q. Gotcha. Okay. So that's a measure of 14 your time?</p> <p>15 A. A measure of my time commitment.</p> <p>16 Q. Understood.</p> <p>17 Take a look at No. 3, which is the study 18 that's sponsored by GlaxoSmithKline.</p> <p>19 Do you see that?</p> <p>20 A. I see it.</p> <p>21 Q. Okay. Next to GlaxoSmithKline there is a 22 parenthetical that says "(approximately \$210,000)."</p> <p>23 Do you see that?</p> <p>24 A. Yes.</p>	<p>Page 71</p> <p>1 unless you consider --</p> <p>2 MR. DAVIS: Hey, Stephen, you might want to mute 3 yourself so you don't get an echo.</p> <p>4 MR. FOWLER: That was -- that was accidental.</p> <p>5 BY THE WITNESS:</p> <p>6 A. -- my wife's law firm which is run out of 7 our house. She is a corporate lawyer. But other than 8 that, no.</p> <p>9 BY MR. DAVIS:</p> <p>10 Q. Let's focus on just one company for a 11 moment, which is Novartis.</p> <p>12 Is it fair to say that -- that Novartis 13 has given you millions of dollars in the form of 14 research grants over the years?</p> <p>15 MR. FOWLER: Objection; form.</p> <p>16 BY THE WITNESS:</p> <p>17 A. No, it wouldn't be fair to say and there 18 is no evidence of that even remotely in my C -- in my 19 CV.</p> <p>20 BY MR. DAVIS:</p> <p>21 Q. Well, let's -- let's take a look at the 22 completed portions of your grants and contracts which 23 starts on Page 26.</p> <p>24 You'll see No. 3 there, which is a study</p>

<p>1 titled "Vitamin D Augmentation of Tekturna in 2 Hypertension"?</p> <p>3 A. Correct.</p> <p>4 Q. Do you see the funder there is 5 Novartis?</p> <p>6 A. Yes, I see it.</p> <p>7 Q. And the funding amount is \$512,000 -- 8 \$512,733?</p> <p>9 A. I see that.</p> <p>10 Q. Okay. And then further down on the same 11 page, No. 5. So --</p> <p>12 A. Let's -- let's -- let's go look at it a 13 little further though. So essentially what happened 14 in this is we got very little of the funding because 15 through the Altitude study and the really crashing and 16 burning of aliskiren, and so the initial funding that 17 they promised they pulled and we only -- we probably 18 didn't get \$25,000 in that. So that was the initial 19 funding amount, but that is not what we received 20 because of what they -- they did.</p> <p>21 Q. And -- and the reason they pulled the 22 funding was -- was why again?</p> <p>23 A. Because they had a couple of studies that 24 came out with the drug aliskiren, a direct renin</p>	<p>Page 74</p> <p>1 \$42,000.</p> <p>2 Do you see that?</p> <p>3 A. Yes, I see that.</p> <p>4 Q. Okay. Did that one actually get funded?</p> <p>5 A. Yeah, that's a legitimate study.</p> <p>6 Q. And then what about on Page 33, a Sandoz 7 study, do you -- do you -- is it your understanding 8 that Sandoz is owned by Novartis?</p> <p>9 A. I have no clue who Sandoz is owned by. I 10 know they are no longer in existence and I've never 11 equated Sandoz with Novartis.</p> <p>12 Q. Okay. Well, nevertheless, do you -- do 13 you see that stun -- study had a funding amount of 14 almost \$760,000?</p> <p>15 A. Where is this?</p> <p>16 Q. Page 33 of your CV, No. 39.</p> <p>17 A. So -- so the -- the MIDAS study, one, I 18 was -- this actually occurred during the time I was a 19 postdoctoral fellow at the University of Minnesota, I 20 was a -- a co-PI with my mentor, and that was very 21 early in my career, so yeah.</p> <p>22 Q. Okay. Let me just rattle off a few other 23 companies, has MSP Singapore Merck made research 24 grants to you?</p>
<p>Page 75</p> <p>1 inhibitor, that really cast a bad light on the drug, 2 and they really just backed off of it, decided that 3 they really weren't going to promote it, and in 4 parallel they weren't going to invest in any science 5 to try to understand the drug better. That's where 6 our study was, is a study to understand the drug 7 better.</p> <p>8 Q. Okay. So -- so why is this in the 9 completed portion of grants and contracts and not in 10 the submitted but unfunded portion?</p> <p>11 A. Well, because it -- it was funded but 12 it -- it's a unique situation in that once it was 13 funded, it was partially funded and then essentially 14 Novartis backed out of the funding commitment when 15 they pretty much abandoned this drug.</p> <p>16 Q. Understood.</p> <p>17 So would that be the same case for No. 5 18 there, also a Tekturna study, \$53,000?</p> <p>19 A. That was a -- a study that I -- I think we 20 probably went on and did that. We weren't the -- the 21 primary -- we were a subcontracting with Beaumont, but 22 we -- we probably got the funding for this.</p> <p>23 Q. Okay. What about the one on Page 29, 24 No. 15, which is a Lotrel study funded by Novartis for</p>	<p>Page 76</p> <p>1 \$42,000.</p> <p>2 Do you see that?</p> <p>3 A. Yes, I see that.</p> <p>4 Q. Okay. Did that one actually get funded?</p> <p>5 A. Yeah, that's a legitimate study.</p> <p>6 Q. And then what about on Page 33, a Sandoz 7 study, do you -- do you -- is it your understanding 8 that Sandoz is owned by Novartis?</p> <p>9 A. I have no clue who Sandoz is owned by. I 10 know they are no longer in existence and I've never 11 equated Sandoz with Novartis.</p> <p>12 Q. Okay. Well, nevertheless, do you -- do 13 you see that stun -- study had a funding amount of 14 almost \$760,000?</p> <p>15 A. Where is this?</p> <p>16 Q. Page 33 of your CV, No. 39.</p> <p>17 A. So -- so the -- the MIDAS study, one, I 18 was -- this actually occurred during the time I was a 19 postdoctoral fellow at the University of Minnesota, I 20 was a -- a co-PI with my mentor, and that was very 21 early in my career, so yeah.</p> <p>22 Q. Okay. Let me just rattle off a few other 23 companies, has MSP Singapore Merck made research 24 grants to you?</p> <p>Page 77</p> <p>1 MR. FOWLER: Form.</p> <p>2 BY THE WITNESS:</p> <p>3 A. I don't recognize that.</p> <p>4 BY MR. DAVIS:</p> <p>5 Q. AstraZeneca?</p> <p>6 MR. FOWLER: Same.</p> <p>7 BY THE WITNESS</p> <p>8 A. It may -- if it's listed on my CV, yeah.</p> <p>9 If not, no.</p> <p>10 BY MR. DAVIS:</p> <p>11 Q. Pfizer?</p> <p>12 MR. FOWLER: Same objection.</p> <p>13 BY THE WITNESS:</p> <p>14 A. I've done research for Pfizer.</p> <p>15 BY MR. DAVIS:</p> <p>16 Q. GlaxoSmithKline and Smithkline Beecham?</p> <p>17 A. If I haven't done research with them, my 18 CV is inaccurate. My CV is accurate.</p> <p>19 Q. Sanofi Aventis?</p> <p>20 MR. FOWLER: Same objection.</p> <p>21 BY THE WITNESS:</p> <p>22 A. Yeah, I've done work with them.</p> <p>23 BY MR. DAVIS:</p> <p>24 Q. Novo Nordisk?</p>

<p>1 MR. FOWLER: Same objection.</p> <p>2 BY THE WITNESS:</p> <p>3 A. If it's on my CV, I've done work with</p> <p>4 them.</p> <p>5 BY MR. DAVIS:</p> <p>6 Q. Have you ever conducted or participated in</p> <p>7 a study that had anything to do with NDMA, NDEA or</p> <p>8 nitrosamines generally?</p> <p>9 A. I have never participated, conducted</p> <p>10 research in that area.</p> <p>11 Q. Okay. Have you ever conducted or</p> <p>12 participated in a study that had anything to do with</p> <p>13 examining the carcinogenic potential of any chemical</p> <p>14 whatsoever?</p> <p>15 A. Directly have I ever done that in -- in</p> <p>16 carcinogenic potential, no, but my training has</p> <p>17 equipped me with the tools to be able to work across</p> <p>18 disciplines and to understand exposure and to relate</p> <p>19 to animal studies.</p> <p>20 Q. Do you have any plans to ever conduct a --</p> <p>21 a study outside this litigation regarding</p> <p>22 nitrosamines, NDMA or NDEA?</p> <p>23 A. It is easy to predict things except about</p> <p>24 the future, and I -- so I don't really try to predict</p>	<p>Page 78</p> <p>1 patients and teaching in that setting, but I have</p> <p>2 never made more than my academic salary from</p> <p>3 consulting.</p> <p>4 Q. What about speaking?</p> <p>5 A. I -- I have never made more outside</p> <p>6 consulting, speaking, or any of those things</p> <p>7 altogether relative to my academic salary.</p> <p>8 Q. You -- you were a speaker for Novartis</p> <p>9 at -- at one point, were you not?</p> <p>10 A. Yeah, years ago.</p> <p>11 Q. Okay. And -- and Novartis is the</p> <p>12 manufacturer of Diovan, Exforge?</p> <p>13 A. Correct.</p> <p>14 Q. The brand manufacturer, correct?</p> <p>15 A. Correct.</p> <p>16 Q. Okay. Were you on the Novartis speaker</p> <p>17 bureau at one point in time?</p> <p>18 A. I may have been on their speakers bureau,</p> <p>19 but it would have been years ago.</p> <p>20 Q. I believe you said you stopped speaking</p> <p>21 generally around 2010, is that right, would that have</p> <p>22 been when you stopped speaking for Novartis?</p> <p>23 A. Any speaking that I've done or their</p> <p>24 speakers bureau would have been before then.</p>
<p>Page 79</p> <p>1 the future, but it is not an area that I have ever</p> <p>2 worked in or likely will.</p> <p>3 Q. Let's go back to your speaking and</p> <p>4 consulting services for pharmaceutical companies for a</p> <p>5 bit.</p> <p>6 Over the various it sounds like decades</p> <p>7 that you did that, can you provide an estimate of how</p> <p>8 much money you received in total for -- for that work?</p> <p>9 MR. FOWLER: Objection to the colloquy.</p> <p>10 Go ahead.</p> <p>11 BY THE WITNESS:</p> <p>12 A. No, I have no clue.</p> <p>13 BY MR. DAVIS:</p> <p>14 Q. Do you think it's hundreds of thousands of</p> <p>15 dollars?</p> <p>16 A. I don't have a clue.</p> <p>17 Q. Okay. Has there ever been a year where</p> <p>18 you've earned more money by speaking, consulting for</p> <p>19 pharmaceutical companies than you did by treating</p> <p>20 patients?</p> <p>21 A. Well, first of all, the way my salary is</p> <p>22 structured, only a portion of my salary comes from</p> <p>23 treating patients. I have salary that's related to</p> <p>24 all of my academic duties that may include treating</p>	<p>Page 81</p> <p>1 Q. Okay. You don't recall being a national</p> <p>2 speaker for Novartis, as they termed it?</p> <p>3 A. I may have been on their speakers bureau</p> <p>4 and given my standing in the field, I may have been a</p> <p>5 national speaker, but I don't remember.</p> <p>6 Q. Okay. Did you receive honoraria or</p> <p>7 payments for that speaking for Novartis?</p> <p>8 MR. FOWLER: Objection; asked and answered.</p> <p>9 BY THE WITNESS:</p> <p>10 A. My time is valuable. When I consult</p> <p>11 typically I receive payment, not 100 percent of the</p> <p>12 time. If it's something that I'm interested in and</p> <p>13 I -- it is more from a scientific perspective, but</p> <p>14 most of the time I do receive compensation.</p> <p>15 BY MR. DAVIS:</p> <p>16 Q. What was the primary purpose in your mind</p> <p>17 of serving as a Novartis speaker?</p> <p>18 MR. FOWLER: Objection to the form.</p> <p>19 BY THE WITNESS:</p> <p>20 A. To educate.</p> <p>21 BY MR. DAVIS:</p> <p>22 Q. To educate?</p> <p>23 A. To educate.</p> <p>24 Q. So that you wouldn't say the primary</p>

- 1 purpose of doing those speakers programs was to get
- 2 paid a lot of money over a short period of time?
- 3 MR. FOWLER: Objection; form, argumentative,
- 4 asked and answered

5 BY THE WITNESS:

6 A. So I have experience and expertise that
7 has been coveted and deservedly so. I'm a straight
8 shooter and an honest broker. And when -- when I
9 lecture and talk, I do it to educate and I'm not
10 promotional. So that's my approach to -- whenever I
11 speak and that's the reason why I don't really engage
12 in that -- in that now because it has just changed and
13 I don't want any part of it.

Page 82

Page 84

Term	Percentage
Alzheimer's disease	98
Stroke	97
Heart attack	96
Diabetes	95
Arthritis	94
Obesity	93
Hypertension	92
Stroke prevention	91
Stroke awareness	90
Stroke risk factors	89
Stroke symptoms	88
Stroke treatment	87
Stroke prevention	86
Stroke awareness	85
Stroke risk factors	84
Stroke symptoms	83
Stroke treatment	82
Stroke prevention	81
Stroke awareness	80
Stroke risk factors	79
Stroke symptoms	78
Stroke treatment	77
Stroke prevention	76
Stroke awareness	75
Stroke risk factors	74
Stroke symptoms	73
Stroke treatment	72
Stroke prevention	71
Stroke awareness	70
Stroke risk factors	69
Stroke symptoms	68
Stroke treatment	67
Stroke prevention	66
Stroke awareness	65
Stroke risk factors	64
Stroke symptoms	63
Stroke treatment	62
Stroke prevention	61
Stroke awareness	60
Stroke risk factors	59
Stroke symptoms	58
Stroke treatment	57
Stroke prevention	56
Stroke awareness	55
Stroke risk factors	54
Stroke symptoms	53
Stroke treatment	52
Stroke prevention	51
Stroke awareness	50
Stroke risk factors	49
Stroke symptoms	48
Stroke treatment	47
Stroke prevention	46
Stroke awareness	45
Stroke risk factors	44
Stroke symptoms	43
Stroke treatment	42
Stroke prevention	41
Stroke awareness	40
Stroke risk factors	39
Stroke symptoms	38
Stroke treatment	37
Stroke prevention	36
Stroke awareness	35
Stroke risk factors	34
Stroke symptoms	33
Stroke treatment	32
Stroke prevention	31
Stroke awareness	30
Stroke risk factors	29
Stroke symptoms	28
Stroke treatment	27
Stroke prevention	26
Stroke awareness	25
Stroke risk factors	24
Stroke symptoms	23
Stroke treatment	22
Stroke prevention	21
Stroke awareness	20
Stroke risk factors	19
Stroke symptoms	18
Stroke treatment	17
Stroke prevention	16
Stroke awareness	15
Stroke risk factors	14
Stroke symptoms	13
Stroke treatment	12
Stroke prevention	11
Stroke awareness	10
Stroke risk factors	9
Stroke symptoms	8
Stroke treatment	7
Stroke prevention	6
Stroke awareness	5
Stroke risk factors	4
Stroke symptoms	3
Stroke treatment	2
Stroke prevention	1
Stroke awareness	0

Page 83

Page 85

Term	Percentage
Organic	50
Non-GMO	70
Artificial	80
Natural	85
Organic	88
Non-GMO	90
Artificial	92
Natural	95
Organic	98
Non-GMO	98
Artificial	98
Natural	98
Organic	98
Non-GMO	98
Artificial	98
Natural	98

Page 86	Page 88
Page 87	Page 89

Page 98	Page 100
[REDACTED]	[REDACTED]

<p>1 Q. Okay. And you are the primary author on 2 this article it appears?</p> <p>3 A. The primary, I'm the primary author on the 4 article.</p> <p>5 Q. Okay. Do you recognize that four of the 6 five other coauthors of yours are Novartis employees?</p> <p>7 A. Yes. They sponsored the study and four of 8 the five, let's see, Dave Calhoun is not, the others I 9 recognize briefly -- I -- I know Hilkert more than the 10 others.</p> <p>11 Q. Did -- this might be a simple question, 12 but by being listed as coauthors, did those Novartis 13 personnel assist in the drafting of the manuscript?</p> <p>14 A. Of course, to be a coauthor you have to 15 participate meaningfully in the development of the 16 manuscript.</p> <p>17 Q. Okay. And you'll see that the study was 18 supported by Novartis Pharma AG?</p> <p>19 Do you see that?</p> <p>20 A. Yes, yes.</p> <p>21 Q. Does that mean financially supported?</p> <p>22 A. Yes.</p> <p>23 Q. Okay. Do you recall the conclusion of 24 this study?</p>	<p>Page 102</p> <p>1 monotherapy?</p> <p>2 A. Yes, I do.</p> <p>3 Q. Okay. Would you agree that that 4 conclusion is favorable to the use of -- of Diovan or 5 valsartan in this case?</p> <p>6 MR. FOWLER: Objection; form, mischaracterizing.</p> <p>7 BY THE WITNESS:</p> <p>8 A. So, would I agree? Here -- here is -- 9 here is what I would say in response to that. That 10 conclusion is supported by the data in the study. If 11 I conclude that any calcium blocker and ACE inhibitor 12 or in combination is not more effective than the 13 calcium blocker alone, I would have to be creating 14 fiction because there is not one combination that you 15 can use like that that would not beat the single drug 16 therapy.</p> <p>17 So making a positive statement that's 18 supported by the data is nothing underhanded, 19 nefarious or misleading. It is just absolutely 20 correct. And this drug to this date is an excellent 21 drug.</p> <p>22 The other --</p> <p>23 BY MR. DAVIS:</p> <p>24 Q. Thank you.</p>
<p>Page 103</p> <p>1 A. Why don't you pull it up.</p> <p>2 Q. Sure.</p> <p>3 Is the -- and I'm paraphrasing here, but 4 is the study conclusion generally that combination 5 therapy of amlodipine val -- valsartan is more 6 favorable than amlodipine monotherapy?</p> <p>7 MR. FOWLER: Objection to the form. And, 8 Counsel, as presented, nobody can read that. That 9 script --</p> <p>10 MR. DAVIS: Oh, my -- my apologies. Let me zoom 11 in a little bit more.</p> <p>12 MR. FOWLER: You have to do better than that.</p> <p>13 It is -- it is still, like, a 6 font. There you go.</p> <p>14 That's getting better. Thank you.</p> <p>15 BY MR. DAVIS:</p> <p>16 Q. Okay. Dr. Flack, if you can't read 17 something let -- let me know because it appears on my 18 screen differently than your screen.</p> <p>19 A. Okay.</p> <p>20 Q. Do you see the -- do you see the statement 21 that combination therapy with amlodipine and valsartan 22 lowered BP more effectively than amlodipine alone with 23 a favorable safety profile comparable to -- or 24 comparable, I guess, rather, to amlodipine</p>	<p>Page 105</p> <p>1 A. The other thing --</p> <p>2 Q. Let me -- let me --</p> <p>3 A. Hold on, Counsel.</p> <p>4 Q. I'm sorry. Go ahead.</p> <p>5 A. The combination not only lowers blood 6 pressure, but the inclusion of valsartan actually 7 minimizes the calcium blocker induced edema. So if 8 this is an example of me saying something favorable, 9 I'm not going to say something not favorable that's 10 not true. This is basically go back to the tables, it 11 is supported solely by the facts, and I rest my case.</p> <p>12 Q. Okay. Thank you for that.</p> <p>13 Do you see the conflict of interest 14 section there?</p> <p>15 A. I see it.</p> <p>16 Q. Okay. You are -- you're JMF, correct?</p> <p>17 A. Yes.</p> <p>18 Q. Okay. And it says that you have received 19 grant and research support and/or as a consultant and 20 speaker for Novartis, Merck, Pfizer, GlaxoSmithKline, 21 AstraZeneca, Solvay, Bristol-Myers Squibb, CVRx, 22 Genzyme, Daiichi Sankyo and -- and Myogen.</p> <p>23 Do you see that?</p> <p>24 A. That's what it says on the paper there.</p>

<p>1 Q. Okay. Is that -- is that statement 2 accurate?</p> <p>3 A. That's what it says on the paper and I 4 give accurate information when I do those.</p> <p>5 Q. Okay. Turning back to your CV, which is, 6 I believe, Exhibit 4, if you have that in front of 7 you.</p> <p>8 Your bibliography, which starts on Page 34 9 and goes through Page 50, it has 194 entries on it.</p> <p>10 Do you see that?</p> <p>11 A. Well, it is 194 peer-reviewed articles, 12 there is probably about 20 book chapters in all, so 13 the 194 is not inclusive of all of my peer reviewed 14 work.</p> <p>15 Q. Okay. Well, that actually catches my next 16 question, which is your report said about 210 or so.</p> <p>17 So were you including in the 210 the 18 articles, peer-reviewed book chapters, is it anything 19 peer reviewed in your report?</p> <p>20 A. It is articles and book chapters.</p> <p>21 Q. Okay.</p> <p>22 A. And if you add 194 and 20, it is actually 23 214.</p> <p>24 Q. Okay. Thank you.</p>	<p>Page 106</p> <p>1 hypertension and cancer, not just any what you contend 2 to be shared risk factors?</p> <p>3 MR. FOWLER: Objection to form.</p> <p>4 BY THE WITNESS:</p> <p>5 A. Well, first of all, it is not what I 6 contend. It is what is actually accepted and known, 7 and obesity, diabetes mellitus, which is common of low 8 physical activity, certain intakes of dietary 9 constituents, from salt to fat, I have studied those 10 things in my hypertension work and am very, very 11 familiar with them and there are shared risk factors 12 for several other diseases, including cancer.</p> <p>13 BY MR. DAVIS:</p> <p>14 Q. Okay. Have -- has any of your -- have any 15 of the 214 articles specifically discussed what you 16 call those shared risk -- risk factors and cancer 17 specifically or is that separate from your published 18 work?</p> <p>19 A. Do you want me to state --</p> <p>20 MR. FOWLER: Objection to form.</p> <p>21 BY THE WITNESS:</p> <p>22 A. Do you want me to say it again? You tell 23 me, because I'm not going to give you an answer any 24 different, so tell me if you want me to say it again.</p>
<p>Page 107</p> <p>1 Have any of those 214 peer-reviewed items 2 that you list in your CV, have they addressed, any of 3 them, NDEA, NDMA or nitrosamines at all?</p> <p>4 A. I don't know. What did your review tell 5 you?</p> <p>6 Q. Well, you -- you are the one who wrote 7 them. I didn't read all of them.</p> <p>8 A. Yeah, your question, of course, I have not 9 done work in that. I have stated previously I haven't 10 done work in NDMA and nitrosamines.</p> <p>11 Q. Okay. How about the association between 12 hypertension and cancer, have any of your 214 13 peer-reviewed items addressed hypertension and cancer 14 specifically?</p> <p>15 A. Indirectly, yes. My -- my work has 16 repeatedly talked about risk factors, lifestyle 17 modification, diet, exercise, physical activity, and 18 those are shared risk factors between hypertension and 19 cancer. So I am intimately familiar with the diet and 20 lifestyle commonalities between the two entities.</p> <p>21 Q. Let me make my question a little more 22 specific.</p> <p>23 Has -- has -- have any of the 214 24 peer-reviewed items specifically addressed</p>	<p>Page 109</p> <p>1 BY MR. DAVIS:</p> <p>2 Q. Well, sure, can -- I guess -- well, let me 3 ask if a different way.</p> <p>4 Can you point me to one of these 214 5 articles where you actually discuss the association 6 between hypertension and cancer specifically?</p> <p>7 MR. FOWLER: Objection; form.</p> <p>8 BY THE WITNESS:</p> <p>9 A. The focus of my articles has not been on 10 hypertension and cancer. The focus of my articles, 11 though, has been on hypertension, lifestyle, diet and 12 comorbidities that have been linked to cancer.</p> <p>13 Does that answer your question?</p> <p>14 BY MR. DAVIS:</p> <p>15 Q. Partially.</p> <p>16 How about have you discussed the link, as 17 you call it, in those articles specifically --</p> <p>18 MR. FOWLER: Objection to form.</p> <p>19 BY MR. DAVIS:</p> <p>20 Q. -- the link between the various things you 21 mentioned and cancer?</p> <p>22 MR. FOWLER: Same.</p> <p>23 BY MR. DAVIS:</p> <p>24 Q. Has that been discussed specifically in</p>

<p>1 any of your articles?</p> <p>2 MR. FOWLER: Same.</p> <p>3 BY THE WITNESS:</p> <p>4 A. I have not written specifically on these</p> <p>5 risk factors and cancer, but I'm intimately familiar</p> <p>6 with them because of my work in hypertension.</p> <p>7 BY MR. DAVIS:</p> <p>8 Q. Okay. Thank you.</p> <p>9 Have any of your articles addressed the</p> <p>10 causation of cancer due to exposure to carcinogenic</p> <p>11 chemicals at all?</p> <p>12 A. Oh, no, I'd have to look at my -- my CV.</p> <p>13 Oh, no, actually, it hasn't, because I don't work in</p> <p>14 that area.</p> <p>15 Q. Okay. Thank you.</p> <p>16 You've mentioned as part of going through</p> <p>17 your -- your educational history that you have a -- an</p> <p>18 MPH. What is an MPH?</p> <p>19 A. I have a Master of Public Health in</p> <p>20 epidemiology. It is the ability to look at datasets,</p> <p>21 work with datasets, study epidemiologic associations,</p> <p>22 and I'm also a clinical trialist as well. But I am</p> <p>23 well versed in all types of studies, from database</p> <p>24 studies to clinical trials and subgroup analysis and</p>	<p>Page 110</p> <p>1 dataset, that's clinical epi, but neither one is a</p> <p>2 randomized trial. You are just observing in different</p> <p>3 settings and reporting and trying to remove as much</p> <p>4 bias as you can.</p> <p>5 Q. So I guess it's in the -- the difference</p> <p>6 is how you go about looking at the -- at the evidence,</p> <p>7 is that what you would say, one is --</p> <p>8 A. No, no. What I said was the -- they are</p> <p>9 both observational, they are just different locations.</p> <p>10 Q. So I guess maybe -- maybe this will help</p> <p>11 me understand.</p> <p>12 Can you just walk me through -- first</p> <p>13 start with an observe -- observational ep- --</p> <p>14 epidemiology study, walk me through kind of what the</p> <p>15 basic ingredients of that would be, and then do the</p> <p>16 same thing for a clinical epi study so that I can</p> <p>17 understand exactly what you are talking about.</p> <p>18 A. So if you look at our work in NHANES, the</p> <p>19 hypertension paper we published in the premier</p> <p>20 hypertension journal in the world, we published the</p> <p>21 first population-based risk estimates for refractory</p> <p>22 and resistant hypertension. We downloaded eight</p> <p>23 cycles of NHANES, that's done every couple of years,</p> <p>24 and it's a public use dataset.</p>
<p>1 anything in between.</p> <p>2 Q. In your words, what is epidemiology?</p> <p>3 A. Epidemiology is a descriptive science by</p> <p>4 and large for the most part. Observational</p> <p>5 epidemiology is not an experiment. And then there are</p> <p>6 things that are linked to epidemiology which become</p> <p>7 more experimental. Most of your clinical databases</p> <p>8 are not. They are -- they are just clinical epi and</p> <p>9 you have to take certain steps to try to make them</p> <p>10 mimic a randomized trial.</p> <p>11 Q. Forgive me if I'm a little slow in</p> <p>12 following you.</p> <p>13 So you -- you've basically discussed I</p> <p>14 guess two forms of practicing epidemiological science,</p> <p>15 one being observational and one being clinical?</p> <p>16 A. Yeah, they are both observational for the</p> <p>17 most part. They are just done in different settings.</p> <p>18 So observational epidemiology is like when we publish</p> <p>19 on the NHANES, National Health and Nutrition</p> <p>20 Examination Survey, which I did with Michael</p> <p>21 Buhnerkempe in our group on hypertension. That's</p> <p>22 observational epi.</p> <p>23 When we report on factors that antagonize</p> <p>24 pharmacologic blood pressure control in the clinical</p>	<p>Page 111</p> <p>1 So what the government does is the</p> <p>2 government goes and employs fancy sampling techniques</p> <p>3 which allow you to make estimates for the entire</p> <p>4 population off of a few thousand people. They have</p> <p>5 removed a lot of the bias by the weight of the sample</p> <p>6 and so you can take those observations and you can</p> <p>7 extrapolate to the entire US population.</p> <p>8 When I do a clinical epi study, typically</p> <p>9 we are using a de-identified clinical database that</p> <p>10 looks at us following patients with certain diseases,</p> <p>11 condition -- conditions and treatment. And the</p> <p>12 problem there is very different because people who get</p> <p>13 different treatments tend to be different from one</p> <p>14 another. There is a reason people get calcium</p> <p>15 blockers versus ace inhibitors versus diuretics.</p> <p>16 So when we work in those datasets, we have</p> <p>17 to undertake a variety of techniques to ensure that</p> <p>18 the conclusions we are making, the observations that</p> <p>19 we are putting forth are unbiased and minimally biased</p> <p>20 as much as we can make them. It is dirtier data, it</p> <p>21 is like dietary data and occupational data where</p> <p>22 you've got a fair amount of confounding issues and</p> <p>23 confounding by indication for various treatments, but</p> <p>24 we know how to do all of that in the dataset that</p>

<p>1 we've been working in. And if we work in a dataset we 2 look at something, and we are not really equipped or 3 the dataset is just not suited for it and we are not 4 in it to try to do something just to get a 5 publication.</p> <p>6 Q. Okay. How do you find -- so in that 7 clinical example, you said that it's, you know, kind 8 of drawing from a range of different datasets. 9 How do you identify those datasets to -- 10 in order to analyze them?</p> <p>11 A. For clinical data we actually have 12 de-identified clinical database that spans about 13 17 years of -- of patients that has longitudinal 14 follow-up that we have published from repeatedly; and 15 also, two, we have project ongoing at my current 16 institution where we've developed one for primary 17 aldosteronism with our endocrinology division which is 18 a -- a clinical and research interest of mine, 19 clinical and subclinical primary aldosteronism.</p> <p>20 Q. So for -- for a task like the one you did 21 in this case where you are looking at a -- a range of 22 articles and trying to draw epidemiological 23 conclusions based on synthesizing them, which -- which 24 one of those epi studies would that fall under?</p>	<p>Page 114</p> <p>1 A. -- than put words in my mouth. 2 I was charged to -- in the area of general 3 causation to examine the literature and try to make a 4 determination whether the exposure to NDMA in the 5 amount and for the duration of time that -- with very 6 generous estimates of what a person could be exposed 7 to was a likely cause of cancer overall or even 8 site-specific cancers, particularly liver cancer. 9 Q. And in -- in doing that, you examined 10 various sources of -- of data, I suppose, we'll call 11 it, right, in the form of -- of studies, a couple of 12 which from Europe you mentioned, correct? 13 A. I examined multiple sources of data and 14 some of them included studies from Europe. 15 Q. Okay. So in -- in doing that task, just 16 kind of put it in -- put the -- put it -- the correct 17 puzzle piece for me, which is what kind of 18 epidemiological study is that that you did? 19 MR. FOWLER: Object to form. 20 BY THE WITNESS: 21 A. First, in this area I didn't do any 22 epidemiological study, so I don't get the question. 23 BY MR. DAVIS: 24 Q. Okay. Well, maybe let's -- let's take it</p>
<p>Page 115</p> <p>1 A. So the strongest evidence in the 2 valsartan, valsartan impurity with NDMA category 3 really falls under the large cohort studies done in 4 Europe in their nationalized health systems where you 5 have exposure data both before and -- the study 6 started and for a period of time you have the claims 7 data and you can make the linkage all in one dataset. 8 You really can't do that very well here in the 9 United States with our fragmented health system 10 outside of maybe some selected populations. 11 Q. Well, let me -- and -- and we'll get into 12 the -- the actual studies in a bit, but I'm just 13 trying to familiarize myself with the process first, 14 which is, like, in -- in terms of -- I mean, would you 15 agree that your assignment in this case was to collect 16 some literature, review it and draw some conclusions 17 holistically based on -- on that literature? 18 MR. FOWLER: Object to the colloquy, object to 19 the form. 20 BY THE WITNESS: 21 A. So it's easier to just ask me what -- what 22 I was charged to do, and -- 23 BY MR. DAVIS: 24 Q. Sure.</p>	<p>Page 117</p> <p>1 this way, which is let me mark a -- an exhibit. This 2 is Exhibit 9 that I'm marking. 3 (WHEREUPON, a certain document was 4 marked Plaintiff-Flack Deposition 5 Exhibit No. 9, for identification, as 6 of 09/28/2021.) 7 BY MR. DAVIS: 8 Q. Do you recognize this as a article that 9 you reference in your bibliography and on which you 10 appear as a coauthor? 11 A. Yes. 12 Q. And it's -- the title is "Individualizing 13 hypertension treatment with impedance cardiography: A 14 meta-analysis of published trials." 15 Do you see that? 16 A. Correct. 17 Q. Okay. Do you recall this particular 18 article that you wrote specifically? 19 A. Yep. 20 Q. Okay. So describe to me what a 21 meta-analysis is? 22 A. So you do individual trials and some of 23 the questions that you want to try to answer often 24 can't be answered in any one trial. So a</p>

<p>1 meta-analysis is a way of combining trials together 2 and reporting them as a single trial, as a single set 3 of data.</p> <p>4 Q. Would that fall under sort of the broader 5 practice of epidemiological science, a meta-analysis?</p> <p>6 A. Yeah, a meta-analysis is a form of -- of 7 epidemiology, but this was beyond observational 8 because here you are doing interventions and combining 9 them but clearly they are epidemiological and 10 statistical principles that you have to adhere to.</p> <p>11 Q. Okay. Let me take you down to the, let's 12 see, this is Page 3 of the article or numbered Page 7.</p> <p>13 Do you see that?</p> <p>14 A. Yes.</p> <p>15 Q. Are -- are you able to read this clearly, 16 Dr. Flack?</p> <p>17 A. Yep.</p> <p>18 Q. Okay. So you'll see -- and I'm just 19 trying to walk through the process from start to 20 finish so I can understand kind of exactly what you 21 did here. But you say: "There have been a number of 22 studies demonstrating the ability of ICG-guided 23 therapy."</p> <p>24 Just briefly, what -- just so we can have</p>	<p>Page 118</p> <p>1 Q. Would that have been -- just for 2 clarification, would those -- would those terms have 3 been all applied, like, it had to meet all of those 4 fields or just one of the -- or were those applied in 5 the alternative?</p> <p>6 A. No, you didn't have to meet all of them.</p> <p>7 Q. Okay. And then there were some inclusion 8 criteria that you discuss below that, correct?</p> <p>9 A. Correct.</p> <p>10 Q. Okay. Were those inclusion criteria 11 preset, meaning that before -- i.e., before you 12 actually applied the -- the keywords into the 13 databases, were the inclusion criteria for those 14 studies preset prior to running the searches?</p> <p>15 A. I don't remember offhand. Typically you 16 do, but one way or the other you -- you are going to 17 get a lot of studies that pop up and you are going to 18 basically end up taking only the studies that fit -- 19 they are, like, randomized trials, so some of these 20 search terms will show up in studies that are 21 observational studies and they are of no use here.</p> <p>22 Q. Okay. But you say typically you do set 23 those inclusion criter- -- criteria prior to running 24 the actual search, correct?</p>
<p>Page 119</p> <p>1 some context here, what -- what is ICG?</p> <p>2 A. Impedance cardiography.</p> <p>3 Q. Okay.</p> <p>4 And then you say: "We conducted a 5 meta-analysis of trials using ICG in the treatment of 6 adults with" -- "with hypertension."</p> <p>7 And then you say: "Initially, we 8 conducted a literature and reference search in 9 Medline, PubMed, and Cochrane databases as well as the 10 internet for studies using ICG in the treatment of 11 adults with hypertension."</p> <p>12 Correct?</p> <p>13 A. Correct.</p> <p>14 Q. Is that what would generally be called in 15 this field like a literature review or a literature 16 search?</p> <p>17 A. When you are looking for trials to 18 include, yes.</p> <p>19 Q. Okay. And then in those databases you say 20 that you applied keywords of hypertension, resistant 21 hypertension, hemodynamics, impedance cardiography, 22 therapy individualization and goal-directed therapy.</p> <p>23 Do you see all those -- all those terms?</p> <p>24 A. Yes.</p>	<p>Page 121</p> <p>1 A. You can set them before or afterwards 2 because at the end of the day you are going to apply 3 it to -- to the -- the studies that pop up and -- and 4 all and it's no mortal sin if you don't do it 5 beforehand as long as you have reasonable criteria.</p> <p>6 Q. Would -- is it -- is it advisable to -- to 7 do it pre running the search to avoid any kind of bias 8 or cherry-picking possibility?</p> <p>9 MR. FOWLER: Objection to form.</p> <p>10 BY THE WITNESS:</p> <p>11 A. Well, first of all, I'm not sure that -- 12 that you are fully grasping what -- what you are 13 asking me. If you apply the -- the -- if you -- if 14 you understand what you want out of -- out of the 15 studies, if you, for example, cherry pick, you are 16 going to get blasted in published literature. So it's 17 really in all likelihood not going to prevent bias 18 in -- in what you include or not. If you have a 19 priori applied criteria for inclusion and those 20 criteria are faulty, when you publish it, you are 21 going to get blasted, and setting it up beforehand 22 doesn't shield you from that.</p> <p>23 What shields you from that is that you 24 have included studies and there is nobody that's</p>

<p style="text-align: right;">Page 122</p> <p>1 saying, Well, you missed this study or you missed that 2 study, okay, that should have been included. That's 3 really, as a journal editor, that's what we are -- we 4 are looking for is were the relevant studies included. 5 And if you've got a gripe with that, what do you think 6 was really missed.</p> <p>7 BY MR. DAVIS:</p> <p>8 Q. Un- -- understood.</p> <p>9 I guess related to that, is it important 10 in doing -- you know, and let's take this ICG study as 11 an example. Let's say there was an outlier study 12 that, you know, you -- you disagreed with the results 13 or they didn't support what the rest of the collected 14 studies showed in your meta-analysis, is it important 15 to -- to address that study nonetheless even if you 16 are discounting it?</p> <p>17 A. You don't include or not include studies 18 based on whether you disagree with the results. You 19 include studies that fit criteria, like are they 20 randomized controlled trials, did they report the 21 outcomes that you are -- you are looking for, and 22 that's why you included them.</p> <p>23 By definition if you do a study enough 24 times you are going to find disparate results simply</p>	<p style="text-align: right;">Page 124</p> <p>1 (WHEREUPON, a certain document was 2 marked Plaintiff-Flack Deposition 3 Exhibit No. 10, for identification, 4 as of 09/28/2021.)</p> <p>5 BY MR. DAVIS:</p> <p>6 Q. Let me know when you have that in front of 7 you, Dr. Flack.</p> <p>8 A. It's in front of me.</p> <p>9 Q. So you mentioned at the outset that of -- 10 of those documents that are on this list, some were 11 sent to you by counsel, some you pulled off of other 12 expert reports, you reviewed the bibliographies of 13 articles that you read and pulled some off that, and 14 that you ran in PubMed a search for valsartan and 15 NDMA.</p> <p>16 Does that capture all of the sources of 17 documents that -- that you collected that made it on 18 to this Exhibit B?</p> <p>19 A. Pretty much.</p> <p>20 Q. Okay. So let's just go through so I have 21 an understanding of -- and I think we can make this a 22 relatively quick exercise where I don't go through 23 each and every document, but I want to get a general 24 sense of how this stuff arrived in your hands.</p>
<p style="text-align: right;">Page 123</p> <p>1 by chance. And if you do a study where there is 2 really no real benefit, if you do it enough times, by 3 chance, you are going to find a -- a statistical 4 significant result.</p> <p>5 So an example, if you go and you are doing 6 epidemiologic studies and you are looking at 10 and 11 7 cancer sites and you keep looking at -- at a bunch of 8 different sites and something pops up positive, weakly 9 positive, that's -- that's very likely to have been a 10 type one error or a false positive.</p> <p>11 And so you have the same corollary here. 12 But we don't exclude or exclude studies because we 13 don't like the results. You include or exclude 14 studies because they don't fit the criteria that will 15 allow you to pool them and to make a -- a single 16 estimate, which by the way when you pool the studies 17 your estimates are more precise, your 95 percent 18 confidence intervals are narrower than they ever are 19 going to be with a single study.</p> <p>20 Q. Got it.</p> <p>21 Let's -- I'm going to mark your materials 22 considered, if I haven't done so already. Let me -- 23 yeah. So I'm marking Exhibit B to your report as 24 Plaintiff-Flack 10.</p>	<p style="text-align: right;">Page 125</p> <p>1 So --</p> <p>2 MR. FOWLER: Objection.</p> <p>3 BY MR. DAVIS:</p> <p>4 Q. -- let's start with MDL Pleadings and 5 General Documents.</p> <p>6 Was that provided to you by counsel?</p> <p>7 A. Anything that's related to the case like 8 that was sent to me by counsel. So let me make it 9 easy for you, that counsel sent me stuff, sent me 10 articles and all, but if you want to go through the 11 list, I'll be happy to do it with you.</p> <p>12 Q. Sure, and let's just make it quick. So -- 13 so MDL Pleadings and General Documents, Written 14 Discovery, provided to you by counsel?</p> <p>15 A. Correct.</p> <p>16 Q. Okay. Deposition Transcripts and Exhibits 17 provided to you by counsel?</p> <p>18 A. Where else would they come from? Of 19 course.</p> <p>20 Q. Okay. Is there a reason that you only 21 reviewed Teva deposition transcripts and exhibits?</p> <p>22 A. I reviewed what I felt was relevant to the 23 case. I reviewed expert testimony coming from people, 24 that -- that are not on the defendant side, and so</p>

<p style="text-align: right;">Page 126</p> <p>1 that characterization that I only saw things from the 2 defendant side is -- is inaccurate.</p> <p>3 Q. Well, let's start with -- with the first 4 point, which is it's your testimony, correct, and 5 sorry if I'm making you repeat this, but that the 6 deposition transcripts and exhibits that were provided 7 to you came to you from counsel?</p> <p>8 A. There is no other source. Yes, they came 9 from counsel.</p> <p>10 Q. Did -- did you ask counsel why they were 11 only providing you Teva depositions and exhibits as 12 opposed to depositions and exhibits used at those 13 depositions for the other manufacturers in this case?</p> <p>14 MR. FOWLER: Objection; form, lacks foundation.</p> <p>15 BY THE WITNESS:</p> <p>16 A. Did I ask him that question, no.</p> <p>17 BY MR. DAVIS:</p> <p>18 Q. Did you make any inquiry at all about why 19 you were only provided Teva depositions and exhibits 20 to those depositions?</p> <p>21 A. No, what --</p> <p>22 MR. FOWLER: Objection; foundation.</p> <p>23 BY THE WITNESS:</p> <p>24 A. No, what I did was I tried to make sure</p>	<p style="text-align: right;">Page 128</p> <p>1 documents as opposed to documents that included those 2 of the other manufacturers?</p> <p>3 MR. FOWLER: Objection; form, asked and 4 answered, lacks foundation.</p> <p>5 BY THE WITNESS:</p> <p>6 A. Many of the documents I received had 7 nothing to do or minimal to do with the question that 8 I was asked to address. They weren't relevant. And 9 that's why I stated multiple times that I did not use 10 any conclusions anywhere else to draw my own 11 conclusions in this case and in my opinion.</p> <p>12 BY MR. DAVIS:</p> <p>13 Q. Okay. How about on Page 4, the Publicly 14 Available FDA Documents, were those provided to you by 15 counsel or did you pull those yourself?</p> <p>16 A. They were provided by counsel, some of the 17 FDA documents I pulled.</p> <p>18 Q. Okay. And then going from Page 4 through 19 the very top of Page 12 there is quite a few 20 literature sites. Would those -- you -- I think your 21 testimony previously was that you may have received 22 those documents from a myriad of sources?</p> <p>23 A. That's correct.</p> <p>24 Q. Is that correct? Okay.</p>
<p style="text-align: right;">Page 127</p> <p>1 that I had the relevant studies and I have stated 2 repeatedly that I did not rely on anybody else's 3 expert testimony to generate my conclusions. So if 4 you extend that is -- those documents are largely 5 irrelevant to me. I may review them, I may get them 6 sent to me, I may not review them. Everything that's 7 sent to me I did not sit and -- and dive to in depth.</p> <p>8 BY MR. DAVIS:</p> <p>9 Q. Okay. Same thing for the other expert 10 reports that you have -- have listed for, I guess, 11 Plaintiff Expert Reports with Exhibits provided to you 12 by counsel?</p> <p>13 A. Some of them I scanned, some of them I may 14 have read, some of them I didn't pay any attention to.</p> <p>15 Q. Okay. Teva Documents provided to you by 16 counsel, below that, on Page 3?</p> <p>17 A. What's your question?</p> <p>18 Q. Was it -- were the Teva Documents listed 19 on Page 3 and 4 under that header, those were provided 20 to you by counsel?</p> <p>21 A. That's why they are on the list, yes.</p> <p>22 Q. Okay. And same question with the 23 Deposition Exhibits and Transcripts, did you make any 24 inquiry as to why you were only provided with Teva</p>	<p style="text-align: right;">Page 129</p> <p>1 Sitting here today, are you able to go 2 through and tell me which ones you received from 3 counsel versus on your own versus some other source?</p> <p>4 A. No.</p> <p>5 Q. Okay. What about the Post-Marketing 6 Periodic Safety Reports on Pages 12, 13, how did those 7 arrive in -- to be -- to -- how did those come to be 8 on this exhibit to your report of materials 9 considered?</p> <p>10 A. Well, they were materials sent to me, 11 that's a difference between materials sent to me and 12 materials considered. So they sent these materials 13 for me and these came from counsel. That -- that 14 actually does not mean that they were considered.</p> <p>15 Q. Gotcha. Okay.</p> <p>16 Is that the same answer with regard to the 17 Bellwether Plaintiff documents from Page 13 to 20, the 18 last page?</p> <p>19 A. My response to you is going to be 20 essentially the same on these documents, yes, so the 21 answer is yes.</p> <p>22 Q. Okay. Okay. Look at the Miscellaneous 23 section on Page 20.</p> <p>24 The very last item says: "This list</p>

<p>1 includes items Plaintiffs' experts relied on. By 2 doing so, Defendants and this expert are not waiving 3 any arguments or objections related to admissibility."</p> <p>4 Do you see that?</p> <p>5 A. On what page?</p> <p>6 I don't know. That's lawyer's speak.</p> <p>7 You've got to translate for me.</p> <p>8 Q. Well, that was -- that was my question is 9 that strikes me as legalese.</p> <p>10 Did you write that or did counsel write 11 that?</p> <p>12 A. I think my response will tell you I didn't 13 write that.</p> <p>14 Q. Okay. Thank you.</p> <p>15 MR. DAVIS: All right. This is a good breaking 16 point in my outline and, in fact, one of my headphones 17 just went out, so can we take our lunch break, if 18 that's okay with you guys?</p> <p>19 MR. FOWLER: Sure, Counsel.</p> <p>20 MR. DAVIS: Okay. All right. Thank you. Do 21 you want to -- when -- 45 minutes okay?</p> <p>22 Let's go off the record first.</p> <p>23 THE VIDEOGRAPHER: The time is 11:57 a.m., off 24 the record.</p>	<p>Page 130</p> <p>1 that paragraph: "...it is my opinion that there is 2 insufficient scientific evidence to establish that 3 trace amounts of NDMA or NDEA in valsartan caused the 4 types of cancers Plaintiffs allege in this 5 litigation."</p> <p>6 Do you see that?</p> <p>7 A. Yes.</p> <p>8 Q. Is -- is that your word that you are using 9 there, "trace," that word "trace," is that your word 10 or did you borrow that from someone?</p> <p>11 A. I think my command of the English language 12 is fairly pretty good, and if you are insinuating that 13 for some reason that I wouldn't be able to phrase how 14 the NDMA would be in valsartan in multiple ways, you 15 are again barking up the wrong tree. This is my 16 report, it has got my name on it, and, again, I hope 17 you've got more than this.</p> <p>18 Q. Well, Doctor, I'm -- I'm asking because 19 I've seen that word appear in a number of manufacturer 20 communications. I'm asking if -- if it's your opinion 21 that, indeed, the amounts of NDMA and NDEA in 22 valsartan are trace amounts or is there --</p> <p>23 MR. FOWLER: Objection to -- objection to the 24 colloquy.</p>
<p>Page 131</p> <p>1 (WHEREUPON, a recess was had 2 from 11:47 to 12:53 p.m.)</p> <p>3 THE VIDEOGRAPHER: The time is 12:53 p.m. -- 4 1:53 p.m. (sic), we are on the record.</p> <p>5 MR. DAVIS: I'm sorry. I didn't -- I didn't 6 hear that. Are we back on the record now?</p> <p>7 THE VIDEOGRAPHER: Yes.</p> <p>8 MR. DAVIS: Okay. Thank you. Sorry, you -- you 9 are cutting in and out a little bit.</p> <p>10 THE VIDEOGRAPHER: I apologize.</p> <p>11 MR. DAVIS: Yeah. Not -- not a problem.</p> <p>12 BY MR. DAVIS:</p> <p>13 Q. Okay. Doctor, we had left off going 14 through your materials considered list, the Exhibit B 15 to your report which is -- which was marked as 16 Exhibit 9 (sic). Let me ask a question.</p> <p>17 Did you look at any test results showing 18 NDMA, NDEA content in any of the valsartan drugs at 19 issue in this litigation?</p> <p>20 A. Not in any detail. I did not pay much 21 attention to that.</p> <p>22 Q. Okay. Let me have you turn, if you would, 23 to Page 31 of your report, which is Section VIII.</p> <p>24 You write starting in the second line of</p>	<p>Page 133</p> <p>1 Go ahead, Doctor.</p> <p>2 BY THE WITNESS:</p> <p>3 A. I have already taken ownership of the 4 word. I can't help it that it was somewhere else, and 5 I'm sure through throughout my report there are 6 probably words that somebody else has used somewhere 7 that I use, but there are a variety of ways that you 8 can express this, and I expressed it in a way that is 9 accurate, and there is -- there is probably more than 10 one way that you can say it.</p> <p>11 BY MR. DAVIS:</p> <p>12 Q. But it is your testimony you didn't 13 actually review any of the act- -- the test results 14 for NDMA, NDEA content in valsartan, correct?</p> <p>15 MR. FOWLER: Objection; mischaracterizes.</p> <p>16 BY THE WITNESS:</p> <p>17 A. Both -- both of the agencies that regulate 18 drugs in the US and in Europe have posted what the top 19 amounts of NDMA were in -- in pills. So you don't 20 have to review granular all of the test results coming 21 from the companies when the regulatory agencies have 22 already done it.</p> <p>23 BY MR. DAVIS:</p> <p>24 Q. Well, how -- how can you be positive</p>

<p>1 without having compared the internal test results to 2 the FDA published test results that those are, in 3 fact, the maximum amounts?</p> <p>4 A. Because the same reason that I trust the 5 FDA when they make decisions and the same reason you 6 trust them when they make decisions that they've done 7 their homework. You know, I've actually worked with 8 the FDA as a member of cardiorenal. They are pretty 9 smart people and they're very talented. So when they 10 and the Europeans post what the top levels of NDMA are 11 in pills and I actually in my simulation used a level 12 even higher than that, I think that that's very 13 commendable.</p> <p>14 Q. And you trust the manufacturers to have 15 provided complete information to the FDA regarding 16 their maximum test levels?</p> <p>17 A. I trust the FDA to get to -- to the bottom 18 of this because the FDA basically is commissioning the 19 testing and so, yes, I trust the FDA and the European 20 society to get to the bottom of this and to understand 21 this problem.</p> <p>22 Q. Okay. Well, while -- while we're talking 23 about the FDA, is it -- so it's your opinion that the 24 word "trace" can mean amounts far in excess of what</p>	<p>Page 134</p> <p>1 BY THE WITNESS: 2 A. Maybe you can give me a definition of what 3 trace and non-trace is, but any definition is going to 4 be arbitrary, and I applied the terminology that I 5 felt was most appropriate and reasonable.</p> <p>6 BY MR. DAVIS: 7 Q. You never reviewed any Mylan-produced 8 documents in preparing your report, did you? 9 MR. FOWLER: Objection; form, lacks foundation.</p> <p>10 BY THE WITNESS: 11 A. Is it on my list?</p> <p>12 BY MR. DAVIS: 13 Q. It's not. 14 A. Okay. 15 MR. FOWLER: Objection.</p> <p>16 BY THE WITNESS: 17 A. If it's not on my list, then I never got 18 it and -- and all, and it is not an area that I needed 19 to review.</p> <p>20 BY MR. DAVIS: 21 Q. Okay. So you wouldn't be for -- aware, 22 for example, that Mylan's own pharmacology/toxicology 23 employees internally were objecting to Mylan's use of 24 the word "trace" to describe their NDMA levels?</p>
<p>Page 135</p> <p>1 the FDA has said as the interim acceptable limits? 2 MR. FOWLER: Objection; form.</p> <p>3 BY THE WITNESS: 4 A. So if I use the word "trace" and the 5 amount is above that, then by implication what you 6 said is -- is true.</p> <p>7 BY MR. DAVIS: 8 Q. Explain to me your reasoning there? 9 A. I've already explained it to you. Do you 10 want me to explain it to you again, because I'm going 11 to give you exactly the same answer? 12 Q. Sure, why not. 13 A. So if the FDA says there is a certain 14 amount in there, the amount in the NDMA pills, at 15 least that some of them is above that, and I'm aware 16 of that and I use the word "trace," then it is 17 unambiguous that I consider it trace. 18 Q. Okay. Even if the levels are hundreds of 19 times in excess of the FDA's interim limits -- 20 MR. FOWLER: Objection.</p> <p>21 BY MR. DAVIS: 22 Q. -- that's trace in your opinion? 23 MR. FOWLER: Objection; form, facts not in 24 evidence.</p>	<p>Page 137</p> <p>1 MR. FOWLER: Objection; form, facts not in 2 evidence.</p> <p>3 BY THE WITNESS: 4 A. So if I don't have any documents from 5 Mylan and I've never communicated with Mylan, the 6 answer is pretty obvious. I -- I would not know that. 7 And whether I call it a trace or an impurity or -- or 8 whatever didn't in -- influence my conclusion.</p> <p>9 BY MR. DAVIS: 10 Q. Okay. You didn't review either any FDA or 11 any health authority guidances on the assessment and 12 control of genotoxic or mutagenic compounds, did you? 13 MR. FOWLER: Objection; form, mischaracterizes.</p> <p>14 BY THE WITNESS: 15 A. I've read material that talked about those 16 things, but that's -- that's not my area of expertise, 17 and it's not something that I'm dwelling on.</p> <p>18 BY MR. DAVIS: 19 Q. So you would not have reviewed the M7(R1) 20 FDA guidance on Assessment and Control of DNA Reactive 21 (Mutagenic) Impurities in Pharmaceuticals to Limit 22 Potential Carcinogenic Risk? 23 MR. FOWLER: Objection; form, mischaracterizes.</p> <p>24 BY THE WITNESS:</p>

<p style="text-align: right;">Page 138</p> <p>1 A. I don't remember a specific document. 2 I've read stuff by the FDA, but I don't remember a 3 specific document. 4 BY MR. DAVIS: 5 Q. Okay. It's not in your -- would you agree 6 with me that it's not in Exhibit 10, which is your 7 list of materials considered under publicly available 8 FDA dot -- documents? 9 MR. FOWLER: Objection; form. 10 BY THE WITNESS: 11 A. I'll take your word for it. 12 BY MR. DAVIS: 13 Q. Okay. So you wouldn't be aware, for 14 example, that the FDA in that document stated that 15 N-nitroso compounds can display extremely high 16 carcinogenic potency? 17 MR. FOWLER: Objection to the form. 18 BY THE WITNESS: 19 A. So the -- the ability of these compounds 20 even in experimental animal models to cause cancer, 21 particularly liver cancer, is not related to are you 22 exposed or are you not. It is done in experiments 23 that have a certain microgram-to-kilogram per day 24 exposure. And so to simply characterize that as,</p>	<p style="text-align: right;">Page 140</p> <p>1 on a microgram-per-kilogram body weight than humans 2 ever have from valsartan that had NDMA in it. 3 MR. DAVIS: I'm going to object and move to 4 strike as nonresponsive. 5 BY MR. DAVIS: 6 Q. The answer was whether you were aware of 7 that statement by the FDA, and that's very simply a 8 yes-or-no question, Doctor. 9 Can you answer it? 10 MR. FOWLER: Objection. Objection. Objection 11 to the colloquy. Objection to counsel's moving to 12 strike in violation of the court's order in this case 13 not to make such statements. So objection noted. 14 Doctor, go ahead. 15 BY THE WITNESS: 16 A. I understand why you want to -- want to 17 strike it because it gets to the heart of the matter 18 and -- and all the heart of the matter is a statement 19 by the FDA, and the FDA has made a -- a whole host of 20 statements about a variety of things. They've also 21 made statements about the excess cancer risk of what 22 they understand the exposure is, okay. And -- and 23 also we could talk about that as well. 24 BY MR. DAVIS:</p>
<p style="text-align: right;">Page 139</p> <p>1 Well, it can, there are certain layers beneath that 2 including the amount, and if you are trying to 3 extrapolate animals to humans, it's an amount per 4 kilogram of body weight which is in -- in my report. 5 And so it's not as simple as -- as you put it out 6 there. And humans, really, through the valsartan 7 exposure to NDMA have come nowhere close to what 8 animals have where you start seeing cancers. 9 BY MR. DAVIS: 10 Q. Well, thank you for that, Doctor, but 11 my -- my question was quite simple. It was whether 12 you were aware that the FDA had said that N-nitroso 13 compounds can display extremely high carcinogenic 14 potency in that document. 15 Is the answer yes or no? 16 MR. FOWLER: Objection; form, hearsay. 17 BY THE WITNESS: 18 A. Well -- well, one, I'm not going to answer 19 it yes or no because it is not a yes-or-no question 20 that you are trying to box me into. Even if you use 21 animal models, there is a certain amount of exposure 22 that you have to have to develop cancer. So in animal 23 models, and you are trying to extrapolate that in 24 humans, the animals are getting a lot more of exposure</p>	<p style="text-align: right;">Page 141</p> <p>1 Q. Well, I'm -- and you just said that you 2 trusted the FDA. 3 So do you trust the FDA's statements then 4 that N-nitro compounds can display extremely high 5 carcinogenic potency? 6 MR. FOWLER: Objection; form, asked and 7 answered. 8 BY THE WITNESS: 9 A. I think what the animal studies would tell 10 you is that under certain conditions at certain 11 exposures that you can induce tumors with these 12 compounds. 13 MR. DAVIS: Counsel, I'm entitled to an answer 14 to my question. The answer is whether he is aware 15 that the FDA has made that pronouncement, and I'm 16 entitled to a simple yes-or-no answer. 17 BY MR. DAVIS: 18 Q. So I'm going to ask it one more time, can 19 I -- can I get a yes-or-no answer, are you aware that 20 the FDA has made that statement? 21 MR. FOWLER: Objection to the colloquy. You've 22 changed your question from are you aware to do you -- 23 do you accept that. And I object to the colloquy, 24 Counsel.</p>

<p style="text-align: right;">Page 142</p> <p>1 BY THE WITNESS:</p> <p>2 A. Well, you are entitled to an answer, but 3 you can't really tell me that I've got to answer it 4 yes or no and it is not a yes-or-no question because 5 if you are asking can it cause cancer, there are 6 conditions under which it can and conditions under 7 which it probably doesn't.</p> <p>8 BY MR. DAVIS:</p> <p>9 Q. Can I get a yes-or-no answer, Doctor, to 10 whether you're aware of whether the FDA has stated 11 that N-nitroso compounds can display extremely high 12 carcinogenic potency, yes or no?</p> <p>13 MR. FOWLER: Objection to form.</p> <p>14 BY THE WITNESS:</p> <p>15 A. Do you want me to repeat my answer?</p> <p>16 BY MR. DAVIS:</p> <p>17 Q. If it is a yes or no, then -- then, yes, 18 I'd like you to repeat it?</p> <p>19 A. You can't compel me to answer a question 20 yes or no when it is not a yes-or-no question. You 21 don't have that right.</p> <p>22 Q. You are either aware of the statement or 23 you are not, Doctor.</p> <p>24 Are you aware of the statement from the</p>	<p style="text-align: right;">Page 144</p> <p>1 MR. FOWLER: Objection; form, mischaracterizing.</p> <p>2 BY THE WITNESS:</p> <p>3 A. What I know is that they are listed as 4 probable carcinogens, okay. They are not listed as 5 definitive carcinogens. And whether they are 6 carcinogenic or not depends on a number of things, 7 including the dose, duration of exposure, and -- and 8 all, and you can't really just talk about it, like, 9 Well, it is biologically plausible, therefore, which 10 is what you are trying to do.</p> <p>11 BY MR. DAVIS:</p> <p>12 Q. So you are aware that, then, it sounds 13 like that the IARC, the World Health Organization and 14 the EPA have all listed NDMA and NDEA as probable 15 human carcinogens?</p> <p>16 A. I don't know, that's pretty much what I 17 just said.</p> <p>18 Q. Sure. And sometimes I'm going to ask very 19 basic questions, but it's -- you know, this is part of 20 the yeoman's work of doing this.</p> <p>21 MR. FOWLER: Object to the colloquy.</p> <p>22 BY MR. DAVIS:</p> <p>23 Q. Turning to Page 31, back to Page 31 of 24 your report, you say that you've:</p>
<p style="text-align: right;">Page 143</p> <p>1 FDA or are you not aware of it?</p> <p>2 MR. FOWLER: Same objection.</p> <p>3 BY THE WITNESS:</p> <p>4 A. I am aware, whether the FDA said it or 5 not, that under the right conditions of exposure, 6 which have not been met in human studies, that you can 7 see cancers in animals and predominantly liver cancer. 8 Okay. So will I trust the FDA? Absolutely. And if 9 they weren't concerned, they wouldn't have been 10 concerned about this.</p> <p>11 BY MR. DAVIS:</p> <p>12 Q. Do you agree that NDMA and NDEA are 13 potential human carcinogens?</p> <p>14 A. What I know about NDMA and NDEA is that in 15 animals at a certain level of exposure they can cause 16 tumors. Okay.</p> <p>17 In humans we are still really waiting on 18 unconfounded data, but surely if you see something in 19 animals that makes you cautious in -- in humans, but 20 we don't have definitive data, certainly not through 21 the valsartan route, that it is causing cancer.</p> <p>22 Q. So it is your testimony then that you 23 agree that it's -- there is a potential for NDMA and 24 NDEA to be human carcinogens?</p>	<p style="text-align: right;">Page 145</p> <p>1 "...conducted a thorough review of the 2 relevant literature on valsartan use and cancer 3 incidence, including the literature cited by 4 plaintiffs' experts in this litigation, and the 5 literature simply does not support a causal 6 association between exposure to trace amounts of 7 nitrosamines and valsartan and cancer development. I 8 will discuss my assessment of the key literature on 9 this subject in turn."</p> <p>10 Did I read your report correctly there?</p> <p>11 A. It is on the paper. You read it 12 correctly.</p> <p>13 Q. Okay. The -- and then what follows in 14 your report, I'm just trying to get an understanding 15 of the overall structure, is you have a section on 16 animal studies, a section on occupational studies, and 17 then you have a section on the valsartan studies, is 18 that correct?</p> <p>19 A. That would be correct.</p> <p>20 Q. Okay. And is it your opinion that you've 21 adequately discussed the key literature as you 22 identified it on Page 31 of your report?</p> <p>23 A. Unless --</p> <p>24 MR. FOWLER: Objection to form.</p>

<p>1 BY THE WITNESS:</p> <p>2 A. -- unless you can prove otherwise or I can</p> <p>3 uncover something that I missed on my own, then the</p> <p>4 answer to that is yes.</p> <p>5 BY MR. DAVIS:</p> <p>6 Q. Are you expressing any kind of opinion in</p> <p>7 your report that the FDA's interim intake limits for</p> <p>8 NDMA or NDEA are unreasonable?</p> <p>9 A. First, I'm not expressing any opinion on</p> <p>10 whether their limits are -- are reasonable or</p> <p>11 unreasonable because they themselves have questions</p> <p>12 about this and there is an uncertainty. So the limits</p> <p>13 are -- are where they are and -- and all, but I'm not</p> <p>14 expressing any -- any opinion -- real opinion on that.</p> <p>15 Q. On Page 39 of your report you have a</p> <p>16 conclusion paragraph there at the end of Section VIII</p> <p>17 that starts with "Thus."</p> <p>18 Do you see that?</p> <p>19 A. I see it.</p> <p>20 Q. "Thus, the available medical and</p> <p>21 scientific literature, including the animal studies on</p> <p>22 NDMA/NDEA exposure and occupational exposure studies,</p> <p>23 and publications examining the effect of NDMA/NDEA in</p> <p>24 valsartan, does not establish that trace amounts of</p>	<p>1 MR. FOWLER: Objection to form.</p> <p>2 BY THE WITNESS:</p> <p>3 A. So -- so usually when there is an issue</p> <p>4 you've missed something that is -- is crucially</p> <p>5 important, it gets pointed out to you what -- what you</p> <p>6 missed. And barring that or barring my discovery of</p> <p>7 that, my conclusion is, is that of the studies that I</p> <p>8 deemed relevant to really come to the conclusions that</p> <p>9 I did, I -- I have included them to the best of my</p> <p>10 ability.</p> <p>11 BY MR. DAVIS:</p> <p>12 Q. Okay. Let's turn to Section III.O of your</p> <p>13 report, which is titled "Epidemiology of Hypertension</p> <p>14 and Cancer."</p> <p>15 I guess my first question is: Are you</p> <p>16 attempting to posit in this section of your report</p> <p>17 what hypertension is a cause of cancer?</p> <p>18 A. First of all, epidemiology doesn't prove,</p> <p>19 and even the biologic plausibility of hypertension per</p> <p>20 se causing cancer, it's one of the things that is</p> <p>21 potentially explaining the association, but it's</p> <p>22 really not at the top of the list.</p> <p>23 Shared risk factors are really a -- a very</p> <p>24 fertile ground and really are more proximal than that,</p>
<p>1 NDMA or NDEA in car" -- "in valsartan cause an</p> <p>2 independent or increased risk of cancer."</p> <p>3 Do you see that?</p> <p>4 A. I see it.</p> <p>5 Q. Is it fair to characterize that paragraph</p> <p>6 as your conclusion regarding the exercise you went</p> <p>7 through in Section VIII of your report?</p> <p>8 MR. FOWLER: Objection to the form.</p> <p>9 BY THE WITNESS:</p> <p>10 A. I think it is pretty obvious that that's</p> <p>11 the case.</p> <p>12 Q. Okay. And that conclusion, as you say, is</p> <p>13 based on the available medical and scientific</p> <p>14 literature, is that right?</p> <p>15 A. Is there anything else? I mean, I am all</p> <p>16 ears if I've missed something. So is there anything</p> <p>17 else I should be considering?</p> <p>18 Q. Well, I'll -- I'll admit, Doctor, I'm not</p> <p>19 the expert, so --</p> <p>20 A. Well, that's clear.</p> <p>21 Q. Thank you.</p> <p>22 A. That's clear.</p> <p>23 Q. How can you be sure that you didn't miss</p> <p>24 some study?</p>	<p>1 but you do -- you do see risk, increased risk of</p> <p>2 cancer, in some cancers you see decreased risk, but</p> <p>3 you see it both in medicated and unmedicated</p> <p>4 hypertension.</p> <p>5 So it is clearly not all -- all drug</p> <p>6 exposure. And even when you can link drug exposures</p> <p>7 at times is because of drugs being used that are more</p> <p>8 likely to be used by people who have these risk</p> <p>9 factors that it doesn't mean the drugs per se are</p> <p>10 causal and it doesn't necessarily say that they are</p> <p>11 not causal. You are -- you are sort of -- you</p> <p>12 don't -- you don't really know and -- and all. So I'm</p> <p>13 saying far beyond that, if you go toward the end of</p> <p>14 this, you'll see five or six or more explanations of</p> <p>15 why you might see an epidemiologic association between</p> <p>16 hypertension and cancer.</p> <p>17 Q. If you turn to Page 25 of your report, you</p> <p>18 call out kidney cancer specifically.</p> <p>19 Is -- is it, in your opinion, that the</p> <p>20 strongest association between kidney cancer and</p> <p>21 hypertension or -- why did you call that one out in</p> <p>22 particular?</p> <p>23 MR. FOWLER: Objection to form.</p> <p>24 BY THE WITNESS:</p>

<p>1 A. So the -- the answer to why that one was 2 called out is really the first part of that sentence. 3 It is that the blood pressure level has been linked to 4 an increased risk of cancer in people with kidney 5 cancer. And all cancers you can't say that for, 6 kidney cancer you can. And right now it is an 7 unexplained explanation -- it is an unexplained 8 observation that -- that has been made that we don't 9 really know exactly what it means. 10 BY MR. DAVIS: 11 Q. Okay. Well, based on the -- you cite a 12 number of articles, and I've -- I've reviewed some of 13 them. 14 My question is: Based on your review of 15 the literature, is the association strongest between 16 kidney cancer and hypertension or is there some other 17 cancer that you think has a stronger association? 18 A. So when you are doing epidemiology, and 19 this is one of the tough things about doing 20 epidemiology, and you go into the hypertensive 21 population, it is not -- very few of them are pure 22 hypertensives. You have hypertensives who are 23 overweight. You have hypertensives who are overweight 24 and don't exercise much. You have hypertensives who</p>	<p>Page 150</p> <p>1 A. I just answered that. The answer is yes. 2 BY MR. DAVIS: 3 Q. What's -- what's the reason for ordering 4 urinalysis for your hypertensive patients? 5 A. So the rationale for ordering a urinalysis 6 is, one, you are going to get an estimate of dipstick 7 proteinuria; two, you are going to get a look at the 8 urine sediment and whether they are casts or red cells 9 or red cell casts which can indicate glomerular 10 disease or other problems in the kidney; three, you 11 are also going to get look at specific gravity, which 12 is an important factor in the kidney's ability to 13 concentrate urine. 14 So -- so there are multiple parameters 15 that you are looking for, things you are looking for 16 when you order a urinalysis. 17 Q. And you mentioned the presence of red 18 blood cells, did you not, as -- as one reason? 19 A. Yes. 20 Q. Okay. And could the presence of red blood 21 cells in the urine be an indicator potentially of 22 kidney cancer? 23 A. The presence of red blood cells in the 24 urine is most likely not kidney cancer. It could be</p>
<p>Page 151</p> <p>1 are taking medicines, not taking medicines. You have 2 hypertensive patients who have diabetes. And a lot of 3 these factors are linked to cancer. 4 So high -- hypertension is -- it's 5 relationship to cancer at least is partially explained 6 by comorbidities. It is not fully understood and 7 clearly why it's related to blood pressure level, 8 biologically everything at this juncture is -- is 9 speculation, but what is not in doubt is that a group 10 of hypertensive patients who have your usual 11 comorbidities have a heightened risk for cancer. 12 Q. Let me ask you a question based on your 13 experience as a -- as a treating physician. 14 When -- when you are treating hypertensive 15 patients, do you often order urinalysis for them? 16 A. So the answer to that question is actually 17 earlier in my report, and when we talk about the usual 18 workup, urinalysis is part of the initial workup 19 that's listed in my report. 20 Q. So is that -- are you telling me that's 21 something you would typically do as part of a standard 22 regimen of -- of treating your patients? 23 MR. FOWLER: Objection; form. 24 BY THE WITNESS:</p>	<p>Page 153</p> <p>1 anywhere from the kidney to the ureters to the bladder 2 to the urethra. You don't really know. But you do 3 know that red cells in the urine are not normal. And 4 so it doesn't tell you anything specific, but it tells 5 you there is a potential problem that needs 6 evaluation. 7 Q. Okay. And what -- what further evaluation 8 or procedures would you recommend for a patient where 9 you saw red blood cells in the urine like that? 10 A. You may do a cystoscopy, you may do a 11 prostate massage and try to ensure there is no 12 infection based on their response to the prostate 13 massage as well as anything that comes out of the 14 urethra in response to that, you may do a CAT scan or 15 an MRI looking for basically masses in the kidney, 16 stones in the kidney. 17 So there are a range of things pro- -- in 18 the urinary tract that can cause red cells to be there 19 and just seeing red cells per se doesn't tell you even 20 remotely what it is, what it is from. 21 Q. Sure. 22 And you mentioned masses in the kidneys as 23 a result of doing, like, a CT scan or an ultrasound. 24 When you say "masses," are you referring potentially</p>

<p>1 for -- looking for tumors?</p> <p>2 A. So you have tumors and many of the masses</p> <p>3 you'll find in the kidney are -- are benign, some of</p> <p>4 them are not benign and are malignant. Certainly</p> <p>5 malignancy is a potential problem that -- that you</p> <p>6 are -- you are concerned about, but it is also a menu</p> <p>7 of problems that you are concerned about of which</p> <p>8 malignancy is one.</p> <p>9 Q. So would you agree with me that in doing</p> <p>10 that urinalysis, you might be led on the investigative</p> <p>11 trail as a physician to an eventual discovery of -- of</p> <p>12 cancer in some cases if you see red blood cells in the</p> <p>13 urine, then take a CT ultrasound, find a mass, and</p> <p>14 then discover that that mass is a malignant tumor?</p> <p>15 A. What I would -- would say about the --</p> <p>16 this is that in the relative sense malignancy will be</p> <p>17 one of the lower probability explanations or findings</p> <p>18 of a workup. It is on the list, it does occur, but in</p> <p>19 a clinical practice most of the people with red cells</p> <p>20 in their urine are not going to have cancer.</p> <p>21 Q. Is -- is endometrial cancer on the list as</p> <p>22 well for red blood cells in the urine?</p> <p>23 A. Well, in women you can bleed out of the</p> <p>24 endometrium and it can contaminate the urine, so</p>	<p>Page 154</p> <p>1 to realize that a number of hypertensive, it is a very</p> <p>2 heterogenous population. You have hypertensive</p> <p>3 patients that are diagnosed, started on medicine, they</p> <p>4 never follow up, they never come back. You get</p> <p>5 hypertensive patients who are under care, keep all of</p> <p>6 their -- their appointments. And you have</p> <p>7 hypertensive patients who drift in and -- and out of</p> <p>8 care. You also have to realize that in the general</p> <p>9 population, even non-hypertensives, many of them are</p> <p>10 actually in the system of care for other reasons. And</p> <p>11 so, again, it is just kind of heterogenous on both</p> <p>12 sides that you have people in and out of the system,</p> <p>13 but if you are hypertensive and you are adherent to</p> <p>14 and getting good follow-up from your doc or doctors,</p> <p>15 you should be in the system more, you should be under</p> <p>16 surveillance more.</p> <p>17 BY MR. DAVIS:</p> <p>18 Q. Okay. You cite the -- and forgive me if</p> <p>19 I'm pronouncing this wrong, the Seretis article</p> <p>20 several times in your report?</p> <p>21 A. About what?</p> <p>22 Q. Are you -- are you familiar with that</p> <p>23 article?</p> <p>24 A. Why don't you pull up what you are talking</p>
<p>Page 155</p> <p>1 absolutely.</p> <p>2 Q. Could those examples be examples of what's</p> <p>3 called detection bias?</p> <p>4 A. Well, detection bias, my understanding of</p> <p>5 it, detection bias is that you've got people under</p> <p>6 surveillance, they are coming in and out of the</p> <p>7 healthcare system, and they are getting not only</p> <p>8 routine tests but sometimes symptom directed tests and</p> <p>9 just by the fact that they are -- they are there, if</p> <p>10 you take 100 people who are in the system on a regular</p> <p>11 basis and 100 people that are in the system less</p> <p>12 intensely or not in the system, you are obviously</p> <p>13 going to find more in the people who are in the</p> <p>14 system. It doesn't mean they have more disease than</p> <p>15 the people who are not in the system, but you have the</p> <p>16 bias in that you can detect it because they are under</p> <p>17 surveillance.</p> <p>18 Q. Would you agree that hypertension patients</p> <p>19 tend to be under a greater degree of medical</p> <p>20 surveillance than your average population?</p> <p>21 MR. FOWLER: Objection; form.</p> <p>22 BY THE WITNESS:</p> <p>23 A. Actually, I'm not sure that I -- I know</p> <p>24 that -- that in -- in any direct comparison. You have</p>	<p>Page 157</p> <p>1 about.</p> <p>2 Q. Sure. If you look at your report, you</p> <p>3 cite Seretis at the end of Footnote 23, at the end of</p> <p>4 Footnote 24, again at Footnote 31c, as an example?</p> <p>5 A. Yep.</p> <p>6 Q. Okay.</p> <p>7 A. What questions can I answer on that?</p> <p>8 Q. Sure. Let me introduce it as an exhibit.</p> <p>9 This is Flack 11.</p> <p>10 (WHEREUPON, a certain document was</p> <p>11 marked Plaintiff-Flack Deposition</p> <p>12 Exhibit No. 11, for identification,</p> <p>13 as of 09/28/2021.)</p> <p>14 MR. FOWLER: Counsel, I am putting the article</p> <p>15 in front of the witness.</p> <p>16 MR. DAVIS: Okay. Thank you.</p> <p>17 BY MR. DAVIS:</p> <p>18 Q. I'd like you to go, if you would, Doctor,</p> <p>19 to the very last page prior to the references, which</p> <p>20 is Page 7.</p> <p>21 A. All right.</p> <p>22 Q. The authors are discussing there this</p> <p>23 detection bias phenomenon and they say:</p> <p>24 "Third, detection bias may also account</p>

<p style="text-align: right;">Page 158</p> <p>1 for some of the reported associations as individuals 2 treated for hypertension are under closer medical 3 surveillance that may lead to easier detection of 4 cancer compared to untreated persons."</p> <p>5 Do you see that?</p> <p>6 A. I see that.</p> <p>7 Q. Is there anything about that statement 8 that you -- you disagree with?</p> <p>9 A. What I would say is pretty much what I 10 said previously, if you were hypertensive and if you 11 follow up, you are in the system and there is a 12 greater risk for -- greater probability of detection, 13 but it depends on who you are being compared to 14 because there are plenty of people who are not 15 hypertensive who are in the medical system for other 16 reasons who also had a similar kind of ability to have 17 an increased probability of detection.</p> <p>18 Here they make a statement and there is no 19 specific reference attached to it. And I'm surprised 20 that as focused you are on references that you would 21 just take the author's word for this.</p> <p>22 Q. I'm sorry. I didn't catch that last 23 sentence. What was that?</p> <p>24 A. I just -- I was surprised, as focused as</p>	<p>1 data.</p> <p>2 Q. Okay. Specifically relating to 3 hypertension and cancer?</p> <p>4 A. Specifically related to what's in that -- 5 in that -- in that sentence, and -- and that's really 6 true literally whether you are hypertensive or not 7 when you are looking at epidemiological studies. 8 There is nothing unique about hypertension here.</p> <p>9 Q. Okay. Do you interpret the authors of 10 this article as discussing specifically the available 11 meta-analyses for -- and which examined hypertension 12 and cancer?</p> <p>13 A. I think these authors did what as a 14 journal editor, associate journal editor I would 15 expect when I am reviewing papers giving authors 16 feedback and at times pushing them then, is that when 17 you write a paper, you -- you basically ex-train -- 18 explain the strengths and potential weaknesses. Okay. 19 And it doesn't mean that everything that is discussed 20 on either side is -- is of equal weight, but you 21 really need to provide the perspectives for a reader 22 who is not steeped in methodology to be able to have 23 some context on what they are reading.</p> <p>24 And so when they discuss the strengths and</p>
<p style="text-align: right;">Page 159</p> <p>1 you are on references, that you would not -- you would 2 take the author's word for this because there is 3 absolutely no reference here, it is just a general 4 statement with no foundation other than speculation.</p> <p>5 Q. Well, that's why I'm asking your -- your 6 opinion, Doctor.</p> <p>7 Is -- is there anything about that 8 statement that you disagree with?</p> <p>9 A. The statement is qualified and -- and all 10 and without a hard reference to that, I would say that 11 it may not be true.</p> <p>12 Q. The -- the very last sentence in the next 13 paragraph says:</p> <p>14 "However, careful interpretation is 15 required as most meta-analyses included a relatively 16 small number of studies, several relative risks had 17 weak or moderate magnitude and may be affected by a 18 residual confounding."</p> <p>19 Did I read that correctly?</p> <p>20 A. Yes, you did.</p> <p>21 Q. Is there anything about that statement 22 that you disagree with?</p> <p>23 A. It is a fairly accurate description of 24 epidemiologic data and what you get in epidemiologic</p>	<p style="text-align: right;">Page 161</p> <p>1 the potential weaknesses, some of the weaknesses that 2 they discussed, and even some of the strengths they 3 discussed, might not necessarily be something that has 4 been studied and you are absolutely definitive of, but 5 you are saying that it's certainly -- this could be 6 part of the explanation of why you are seeing it line 7 up more on the positive side or -- or the negative 8 side and to be considered. And I think that they did 9 a very reasonable job in -- in doing that in this 10 paragraph.</p> <p>11 Q. Okay. Well, let's -- let's put you in the 12 shoes of if you were the editor reviewing this article 13 for acceptance, if they had not done that, would you 14 have approved that article for -- for publication?</p> <p>15 A. When I'm reviewing articles as an 16 associate editor and forwarding them to my editor with 17 my recommendations, whether an article should be 18 accepted, rejected or not, and sometimes I sat for 19 two, three, maybe four rounds with the investigators 20 going back and forth about, you know, Here is what the 21 reviewer said, here is what I'm saying, and it's still 22 not taken care of, what I'm looking for is -- is 23 balance. I'm looking for a -- a fair, expansive 24 explanation and to the degree that you can place in a</p>

<p style="text-align: right;">Page 162</p> <p>1 hierarchy some of the reasons that you are giving, 2 fine, if you can't, just be -- be fair and -- and be 3 expansive in what you include. 4 So if -- if you don't include some of the 5 things that could impact the relative risks that they 6 saw, then you are -- are not being expansive in your 7 explanation. 8 So the way I edit papers, they would have 9 to address both the strengths and the weaknesses, 10 potential weaknesses in a -- a manner to the degree 11 that -- that I understand them applicable to what they 12 are writing. 13 Q. Let's take the proposition that you put 14 forth in -- in Section III.O of your report at -- at 15 face value, which appears to be, and you can -- and I 16 expect you will obviously correct me if I'm 17 misunderstanding you here, but you are saying that 18 this is a population of people, hypertensives mainly, 19 who are already at a greater risk of cancer than the 20 rest of the world, is that right? 21 A. The best epidemiologic evidence we have in 22 hypertensive populations is that there are multiple 23 cancers in multiple kinds of hypertensive patients 24 medicated, unmedicated, that are linked either to the</p>	<p style="text-align: right;">Page 164</p> <p>1 cancer, because the devil is in the details. It 2 depends on the exposure. 3 BY MR. DAVIS: 4 Q. Well, don't you think, though, it is 5 important not to unnecessarily add to the risk that 6 hypertensives would -- you contend already have a 7 higher risk of -- of cancer, don't you think it's 8 important not to unnecessarily add to that risk? 9 MR. FOWLER: Objection; form. 10 BY THE WITNESS: 11 A. So, I would just answer you like this. If 12 you can point me to any -- any data that says that the 13 amount of exposure from valsartan with NDMA in it has 14 increased cancer risk, I'd like to know what it is. 15 If you have data like that, then we can -- we can 16 discuss it. 17 If you are asking me in a theoretical 18 and -- and all, I would just say is there data to 19 support that position and I'll hang up and listen. 20 BY MR. DAVIS: 21 Q. You don't think that NDMA or NDEA 22 decreased cancer risk, do you? 23 A. So what kind of question is that? I mean, 24 do I think it decreases cancer risk? There is no</p>
<p style="text-align: right;">Page 163</p> <p>1 presence or absence of hypertension and/or the level 2 of blood pressure. That doesn't tell you why they are 3 at apparently higher risk. It just tells you they 4 are. 5 Q. Don't you think it's important that, 6 particularly for these people, not to -- to add to 7 that risk unnecessarily? 8 MR. FOWLER: Objection; form. 9 BY THE WITNESS: 10 A. The -- again, I think I know where you are 11 going and I think you read my report and the amounts 12 of NDMA found in valsartan at the exposure levels and 13 coupled with the epidemiologic studies, there is no 14 consistent evidence that the amount of NDMA in 15 valsartan consumed by people in roughly four and a 16 half years, even if they took the max dose at super 17 high levels compared to what the FDA said, even 18 approached, they are probably 30, 40 times lower than 19 what you get in animal models where you start seeing, 20 on a microgram-per-kilogram basis, cancer. 21 So, again, this is an argument that has 22 context to understand it and it is a different 23 question than is it biologically plausible that NDMA, 24 nitrosamines and other similar substances can cause</p>	<p style="text-align: right;">Page 165</p> <p>1 evidence that it decreases cancer risk. 2 Q. So the two options in your mind are either 3 potentially no effect or a carcinogenic effect, 4 correct? 5 MR. FOWLER: Objection; form, mischaracterizes. 6 BY THE WITNESS: 7 A. Depending on the circumstances, those are 8 going to be the two outcomes that -- that you would 9 be -- be looking at. 10 BY MR. DAVIS: 11 Q. And you -- do you not think that it -- 12 it's important for hypertensives who you claim to be 13 already at a higher risk of cancer not to 14 unnecessarily add to that risk? 15 MR. FOWLER: Objection; form, asked and 16 answered. 17 BY THE WITNESS: 18 A. Again -- again, based on the evidence we 19 have in humans, the -- in a case is specious at best. 20 We have arsenic in our drinking water. We have 21 acceptable levels of arsenic. We have contaminants, 22 we have impurities, we have things that are in our 23 drugs, including NDMA, that are -- are there and -- 24 and all. So the -- the argument is not are they there</p>

<p>1 or are they not there. The argument is -- is more 2 nuanced than that.</p> <p>3 BY MR. DAVIS:</p> <p>4 Q. Is it your opinion that the presence of 5 nitrosamines in drugs is unavoidable or a necessary 6 evil that we have to contend with?</p> <p>7 MR. FOWLER: Objection; form, beyond the scope.</p> <p>8 BY THE WITNESS:</p> <p>9 A. Well, that's actually not an area that I'm 10 going to offer much of an opinion on. It -- it 11 must -- there must be some difficulty because we've 12 had multiple products that have shown up with it in 13 there from reputable manufacturers.</p> <p>14 So there are multiple ways that it can get 15 in there and -- and all and it's not all even the 16 manufacturing process. Some of it can occur -- occur 17 afterwards. So, it -- again, it's just multiple ways 18 that NDMA can get in there.</p> <p>19 BY MR. DAVIS:</p> <p>20 Q. But you've -- you've done no independent 21 analysis is what you are saying?</p> <p>22 MR. FOWLER: Objection; form.</p> <p>23 BY THE WITNESS:</p> <p>24 A. So what I've done is I have used</p>	<p>1 limit.</p> <p>2 BY MR. DAVIS:</p> <p>3 Q. Have -- you have -- have you done any 4 research into the FDA's thinking on why they set 5 acceptable interim -- interim limits?</p> <p>6 A. I asked the -- the question. They set 7 acceptable limits because getting to zero, just like 8 anything, zero in the arsenic in -- in water may not 9 be -- be feasible to actually do. Okay. And so if 10 they are not kicking drugs off the market because they 11 have some NDMA in them, it is a threshold level that 12 they are -- they are setting.</p> <p>13 Q. Have you -- have you done any research to 14 determine whether it was infeasible for these 15 manufacturers to manufacture valsartan free and clear 16 of nitrosamines?</p> <p>17 MR. FOWLER: Objection; form, beyond the scope.</p> <p>18 BY THE WITNESS:</p> <p>19 A. Well -- well, first of all, that's not my 20 area of expertise. Secondly, even the FDA, they had a 21 conference on this, even the FDA tells you that the 22 NDMA can come in through the manufacturing process, it 23 can come in even after the drug has been packaged, and 24 so finding NDMA does not necessarily mean that it</p>
<p>1 FDA/European data and even augmented the -- the top 2 level of exposure per 320-milligram pill and made the 3 assumption, which is not true, that everybody would be 4 up at 320-milligram pill containing the levels at 5 really higher levels of NDMA and calculated an 6 exposure and related that to the body weight and 7 compared it to animal models.</p> <p>8 And you know what's in my report and you 9 know that the animal models are a lot more of an 10 exposure and you also know that in the human studies 11 the evidence that this exposure to valsartan causes 12 cancer is firstly nonexistent.</p> <p>13 BY MR. DAVIS:</p> <p>14 Q. Well, let's -- you jumped around a little 15 bit there. Let -- let's stick with the beginning part 16 of your statement, and -- and my question -- follow-up 17 question to that is: Are you aware that the FDA's 18 position is that there should be zero nitrosamines in 19 any of these valsartan drug substances?</p> <p>20 MR. FOWLER: Objection; form, colloquy, facts 21 not in evidence.</p> <p>22 BY THE WITNESS:</p> <p>23 A. So if the FDA's position is that, somebody 24 needs to explain to me why they set an acceptable</p>	<p>1 automatically was there from the manufacturing 2 process. It certainly could be and it could be other 3 causes of it. And, again, the FDA is not setting a 4 zero tolerance on this and there is a reason they are 5 not setting a zero tolerance on this. They are 6 setting an acceptable limit.</p> <p>7 BY MR. DAVIS:</p> <p>8 Q. Well, they -- they have in a way set a 9 zero tolerance by saying it's their expectation 10 that -- that drug products should contain zero 11 nitrosamines.</p> <p>12 Are you not aware of that?</p> <p>13 MR. FOWLER: Objection; form, facts not in 14 evidence.</p> <p>15 BY THE WITNESS:</p> <p>16 A. Well, what I'm aware of is that there are 17 compounds still on the market today that have 18 detectable NDMA that the FDA has not taken off the 19 market. And so while they may have discussions and 20 they are very bright people, very talented, much more 21 so than people give them credit for, there is a reason 22 they have a detectable -- they have a limit of what 23 you can be exposed to. And in a perfect world, you'd 24 like zero arsenic in your water and you'd like zero</p>

<p style="text-align: right;">Page 170</p> <p>1 NDMA, but there is a reason they have set a -- a limit 2 and there is a reason that drugs that are under that 3 limit are -- are not being pulled off but still may 4 have detectable NDMA.</p> <p>5 BY MR. DAVIS:</p> <p>6 Q. There is no manufacturer of water out 7 there, is there?</p> <p>8 MR. FOWLER: Form.</p> <p>9 BY THE WITNESS:</p> <p>10 A. Actually, yes, there is. There are people 11 who do things to water in all -- and in the public 12 sphere our water, drinking water is tested and there 13 are acceptable levels of potential carcinogens, 14 including arsenic, in our water.</p> <p>15 BY MR. DAVIS:</p> <p>16 Q. Have you done any research whatsoever to 17 determine -- have you read any of the -- let me strike 18 that.</p> <p>19 Have you -- have you read any of the root 20 cause reports of any of these manufacturers as to 21 exactly how NDMA or NDEA got in there?</p> <p>22 MR. FOWLER: Objection; form, outside the scope.</p> <p>23 BY THE WITNESS:</p> <p>24 A. Actually, I have. I've read multiple</p>	<p style="text-align: right;">Page 172</p> <p>1 Q. Okay. Let's go to Section VII of your 2 report, Valsartan Recall and Impact on Hypertension 3 Patients.</p> <p>4 A. Okay.</p> <p>5 Q. You use the word "unexpected" in 6 describing the NDMA, NDEA contamination several times. 7 Do you see that?</p> <p>8 A. Yes.</p> <p>9 Q. Did you do any investigation or 10 independent analysis on your own to try to figure out 11 whether, in fact, the NDMA or NDEA contamination was 12 unexpected?</p> <p>13 A. Well, certainly the FDA used the 14 terminology "unexpected," and secondly, I'm -- I'm all 15 ears if you can tell me what independent analysis I 16 should have done or would have been able to do to -- 17 to make that determination.</p> <p>18 Q. If, for example, one of these 19 manufacturers had actual knowledge of NDMA 20 contamination a long time before the recall, would 21 that still qualify as unexpected in your opinion?</p> <p>22 MR. FOWLER: Object. Objection; form, facts not 23 in evidence.</p> <p>24 BY THE WITNESS:</p>
<p style="text-align: right;">Page 171</p> <p>1 sources of how the NDMA potentially got in there and I 2 also know it can get in through multiple channels. 3 And, so, yes, I mean, I -- I basically have read 4 material.</p> <p>5 BY MR. DAVIS:</p> <p>6 Q. Okay. Where -- where in your materials 7 considered list did you review the manufacturer of 8 root cause analyses?</p> <p>9 A. There are documents in there that the FDA 10 has where they discuss it where it came in there and 11 there are articles that are listed that discuss how it 12 appears the NDMA got -- got in there and those are 13 articles I read.</p> <p>14 Q. Is it your contention that you've reviewed 15 anything that suggests to you that any of these 16 manufacturers are unable to figure out how to 17 manufacture valsartan free and clear of nitrosamines?</p> <p>18 MR. FOWLER: Objection; form, beyond the scope.</p> <p>19 BY THE WITNESS:</p> <p>20 A. I think it is a question you need to ask 21 them. I have no insight into their manufacturing 22 processes and I'm not equipped to render an opinion on 23 that.</p> <p>24 BY MR. DAVIS:</p>	<p style="text-align: right;">Page 173</p> <p>1 A. Well -- well, first of all, the date of 2 the recall I'm sure is not the first date that the FDA 3 had communication with companies, but, again, that's 4 beyond my -- my scope. For us who depend on the FDA 5 to police our drug supply, it absolutely was -- was 6 unexpected. And FDA used the terminology "unexpected" 7 as well. So if I'm in bad company, I'm in bad company 8 with the FDA on that.</p> <p>9 BY MR. DAVIS:</p> <p>10 Q. What about if one of these manufacturers' 11 raw material suppliers explicitly warned them of the 12 potential for nitrosamine formation in the very 13 process that they were doing to make valsartan as far 14 back as 2014, would that qualify still as unexpected 15 in your opinion?</p> <p>16 MR. FOWLER: Objection; form, facts not in 17 evidence, scope.</p> <p>18 BY THE WITNESS:</p> <p>19 A. How would you expect me to know what a 20 manufacturer told anybody? So it would still be 21 unexpected to me because that is not any kind of 22 communication I would have had any access to.</p> <p>23 BY MR. DAVIS:</p> <p>24 Q. Okay. So you've done no independent</p>

<p>1 analysis that leads you to a conclusion that the 2 contamination was indeed unexpected, you're just 3 relying on what you contend to be the FDA's use of 4 that word, correct?</p> <p>5 MR. FOWLER: Objection; form, mischaracterizes.</p> <p>6 BY THE WITNESS:</p> <p>7 A. Actually, no, what I am saying is given 8 what I was privy to and my dependence on the FDA for 9 safeguarding our -- our drug supply that when this 10 became known, it was unexpected.</p> <p>11 BY MR. DAVIS:</p> <p>12 Q. So you're -- but that's not your -- 13 your -- you are not describing any -- any independent 14 analysis or documents that you've reviewed to actually 15 determine whether it was unexpected for any of these 16 manufacturers, isn't that right?</p> <p>17 A. My reporting of being unexpected is from 18 the vantage point that I sit in. I do not see 19 documents like that. And so from my vantage point, it 20 was unexpected. The FDA sees more than I do and from 21 their advantage point it was unexpected as well.</p> <p>22 Q. But you're not sure what the FDA reviewed 23 at all in making or not making that statement?</p> <p>24 MR. FOWLER: Objection; form, beyond the scope</p>	<p>Page 174</p> <p>1 MR. FOWLER: Objection to form, outside the 2 scope, mischaracterizing, lack of foundation.</p> <p>3 BY THE WITNESS:</p> <p>4 A. I was given a -- a narrow assignment and I 5 looked at documents that were relevant to 6 understanding my focused assignment. There are people 7 who have expertise in these areas about manufacturing 8 that far exceed mine and those questions are best 9 either asked of them or -- or somebody involved in the 10 manufacturing.</p> <p>11 I had more documents than I ever looked at 12 in all and I -- I had plenty of documents to come to 13 the conclusions, and unless you can tell me that I 14 have really missed something of critical importance or 15 made an error in judgment, I mean, this is just coffee 16 house crap.</p> <p>17 BY MR. DAVIS:</p> <p>18 Q. The last sentence of that Section VII 19 says: 20 "I did not witness any patients have an 21 adverse effect as a result of the NDMA, NDEA 22 impurities found in valsartan."</p> <p>23 Do you see that?</p> <p>24 A. Yes.</p>
<p>Page 175</p> <p>1 of this general causation expert.</p> <p>2 BY THE WITNESS:</p> <p>3 A. So what -- what I do know from having 4 worked with the FDA, and in an ad hoc basis in -- as a 5 standing member of FDA Cardiorenal Advisory Panel, is 6 they are -- they are awfully smart and they are 7 awfully talented and, if anything, they are -- are 8 tilted to be harder on -- on industry than, you know, 9 than -- they probably go a bit the other way, and it's 10 important that they do that because it helps safeguard 11 us from catastrophes.</p> <p>12 So I have tremendous respect for not just 13 sitting around looking at stuff on the internet. I've 14 been to the FDA, I've worked with the FDA, and I know 15 how it works and I've interfaced with their -- their 16 scientists, so I have a pretty informed opinion when I 17 say I have great trust in the Food and Drug 18 Administration.</p> <p>19 BY MR. DAVIS:</p> <p>20 Q. You had the opportunity to ask counsel for 21 internal documents of these manufacturers or 22 depositions, for example, of their witnesses that were 23 taken where these topics were discussed.</p> <p>24 Why did you not ask for any of that?</p>	<p>Page 177</p> <p>1 Q. Have you had any hypertension patients of 2 yours receive a cancer diagnosis in the last five, six 3 years?</p> <p>4 MR. FOWLER: Objection; form.</p> <p>5 BY THE WITNESS:</p> <p>6 A. I'm sure I have, yeah.</p> <p>7 BY MR. DAVIS:</p> <p>8 Q. For any of those patients, did you do any 9 work to rule out NDMA or NDEA contamination as having 10 contributed -- contributed to their cancer diagnosis?</p> <p>11 A. Perhaps you can explain to me how you rule 12 out a cause of cancer in an individual that can't be 13 found in hundreds of thousands of people.</p> <p>14 Q. Well, you appear to be ruling out NDMA, 15 NDEA impurities by making that statement that you did 16 not witness any adverse effects. I'm trying to get to 17 what you mean by that sentence?</p> <p>18 A. Well --</p> <p>19 MR. FOWLER: Objection, argumentative.</p> <p>20 BY THE WITNESS:</p> <p>21 A. -- well, first of all, the -- the adverse 22 effect has to do with when the drug is recalled, and 23 if I'm not mistaken, it says "Valsartan Recall and the 24 Impact on Hypertension Patients." It's not talking</p>

<p>1 about cancer. It is really talking about what went on 2 with patients when we found out that there were lots 3 that had impurities in it and that patients needed 4 alternative therapies. That's really where my 5 comments are.</p> <p>6 And when I say that I didn't see any harms 7 to patients during this transition, No. 1, we have 8 plenty of ARBs on the market. Valsartan, irbesartan 9 and losartan were involved in the recall of the 10 generics.</p> <p>11 Two, I've still got five or so other ARBs 12 to choose from. There is zero problem with 13 substitute. Okay. So the transition was fairly 14 seamless once we found out there was a problem between 15 us and the pharmacies and getting people onto other -- 16 other therapies.</p> <p>17 The danger is they read about lawsuits, 18 they read about stuff and -- and potentially causing 19 cancer and what they -- they will do sometimes is stop 20 the drugs on their own, okay. I saw people do that. 21 I didn't see anybody get specifically harmed from 22 that, but that's not something you really, really want 23 to do.</p> <p>24 So my -- my -- I stand behind my statement</p>	<p>Page 178</p> <p>1 NDMA. If you have anybody who tells you that they 2 know how to do that, they are pulling your leg, okay. 3 You -- you can't do that, but what I can do, because I 4 take care of patients and we talk to patients and I 5 see them in my practice is I know when I've got a 6 problem.</p> <p>7 Back in the 1990s when they were talking 8 about calcium channel blockers, increased 9 cardiovascular risk caused cancer, whatever, I had 10 patients flushing their nifedipine, okay, but as a 11 practitioner who goes in and closes the door and takes 12 care of people, I know how to deal with that.</p> <p>13 Fast forward to this valsartan recall, 14 when the valsartan recall happened, we had zero 15 problem transitioning patients to appropriate 16 alternative therapies. Our biggest problem was people 17 who read something online or heard about it on the 18 news or in the newspaper or wherever and decided on 19 their own not to take the drugs because they were 20 basically weighing the short-term (sic) risk of 21 continuing to taking the drug and minimizing the 22 short-term risk of not taking the drug, which is much 23 more substantial.</p> <p>24 BY MR. DAVIS:</p>
<p>Page 179</p> <p>1 that I really didn't see anybody harmed in making the 2 transition from these drugs that had NDMA in it to 3 other ARBs.</p> <p>4 BY MR. DAVIS:</p> <p>5 Q. Okay. And I'm jugs trying to get to the 6 bottom of what you did to back that statement up and 7 what you mean by it.</p> <p>8 So it sounds like you are just saying that 9 that's purely observational on your part, that you did 10 not witness any adverse effect as a result of 11 nitrosamines, it is not that you actually did some 12 kind of follow-up or a specialized treatment regimen 13 for any of those patients that were on recalled 14 valsartan products to rule out NDMA or NDEA as -- as 15 causing their cancer, correct?</p> <p>16 MR. FOWLER: Objection; form, foundation, 17 compound.</p> <p>18 BY THE WITNESS:</p> <p>19 A. So, again, I'll go back to the heading 20 here, it says Valcar -- "Valsartan Recall and Impact 21 on Hypertension Patients." So it's really talking 22 about the recall. And what was the impact of the 23 recall on hypertensive patients. You are trying to 24 take it back to I should have done something about</p>	<p>Page 181</p> <p>1 Q. Okay. I appreciate that, Doctor, but 2 my -- my question, and I'm not by any means suggesting 3 you should have done -- I mean, you're a hypertension 4 specialist, you are not an oncologist, I'm not 5 suggesting you should have done any work to rule out 6 NDMA or NDEA contamination as having contributed to 7 any cancer that any of your patients received as a 8 result of being on recalled valsartan products.</p> <p>9 I'm just trying to clarify that you did 10 not do any of that. Is that -- is that right? And 11 I'm not saying I expected you to. I'm just saying you 12 did not, is that right?</p> <p>13 MR. FOWLER: Objection to colloquy. Objection 14 to colloquy and form.</p> <p>15 BY THE WITNESS:</p> <p>16 A. That's exactly what you are saying, and my 17 response to that is if you can tell me what you can do 18 to rule this out at an individual patient level, I am 19 all ears because there is nobody, I don't care what 20 your training is, who knows how to do that.</p> <p>21 BY MR. DAVIS:</p> <p>22 Q. Okay. So the answer is -- is, no, that 23 you did not make any effort to rule out NDMA or NDEA 24 contamination for any of those patients?</p>

<p>1 MR. FOWLER: Objection; foundation, 2 mischaracterizing. 3 BY THE WITNESS: 4 A. Anyone who was on a drug product that had 5 unacceptable limits of NDMA in it, we got them 6 transitioned. Beyond that, the ability to 7 investigate -- I'm not -- I'm not into wasting my 8 time. I'm into spending time on things that can help 9 people and help us take care of them. There is no way 10 at an individual patient level that you can rule out 11 anything except get them off the drug and keep them 12 under surveillance. 13 BY MR. DAVIS: 14 Q. Okay. And it's your -- I think you've 15 alluded to this a couple of times, but your practice 16 was able to swiftly and seamlessly transition patients 17 to an appropriate alternative therapy? 18 A. You know, we did that, and if we couldn't 19 do that, we would be awfully dumb, which we aren't. 20 Q. Okay. Are any of your patients still on 21 valsartan products that have nitrosamines in them? 22 MR. FOWLER: Objection; form. 23 BY MR. DAVIS: 24 Q. To your knowledge?</p>	<p>Page 182</p> <p>1 Q. Is it fair to -- to say that Section IX of 2 your report is kind of a synthesis, and I'm just 3 trying to understand where you are coming from there, 4 but Section IX of your report is a synthesis of your 5 opinions that you reach in Sections VIII and 6 Sections III.O of your report? 7 MR. FOWLER: Objection to form. 8 BY THE WITNESS: 9 A. So why don't you clarify what you are 10 asking me there. 11 BY MR. DAVIS: 12 Q. Sure. 13 So in -- in Section III.O of your report, 14 you put forth opinions on hypertension and can -- and 15 cancer and there being risk factors. In Section VIII 16 of your report you posit that there is no causal 17 relationship between NDMA, NDEA in valsartan and 18 cancer. In Section IX of your report is a synthesis 19 of those two sections where you posit that it is more 20 likely that patients developed these cancers from 21 their status as being hypertensive as opposed to 22 exposure to nitrosamines. 23 Is that a fair reading of your report, 24 that it synthesizes those two sections?</p>
<p>Page 183</p> <p>1 A. To my knowledge, no. 2 Q. Did you keep a single one of your patients 3 on recalled valsartan a day longer than they had to be 4 on recalled valsartan? 5 MR. FOWLER: Objection to the form, foundation. 6 BY THE WITNESS: 7 A. No. We transitioned them as soon as we 8 could. 9 MR. DAVIS: Let me take a -- a quick break to 10 review my notes. I'm getting close to the end here. 11 What do you say, five minutes? 12 MR. FOWLER: That's fine, Counsel. 13 MR. DAVIS: Sure. Let's go off the record. 14 THE VIDEOGRAPHER: The time is two o'clock p.m. 15 We are off the record. 16 (WHEREUPON, a recess was had 17 from 2:00 to 2:23 p.m.) 18 THE VIDEOGRAPHER: It's 2:23 p.m. We are on the 19 record. 20 BY MR. DAVIS: 21 Q. Dr. Flack, before I wrap up, I just wanted 22 to touch on briefly Section IX of your report, which 23 appears at Page 39. 24 A. Okay.</p>	<p>Page 185</p> <p>1 MR. FOWLER: Objection; form, vague. 2 BY THE WITNESS: 3 A. So -- so I'll -- I'll state what I'm 4 trying to say. 5 When you do -- you look at the Pottegård 6 study, you look at the Gomm study, you basically 7 firstly find nothing there in humans when they've been 8 studied with exposed and unexposed valsartan patients. 9 And so you really don't have virtually any evidence in 10 humans. And then you look at a group of people who, 11 whether they are taking valsartan or not, you know 12 that they have higher risk. In the absence -- that 13 statement is more about the absence of data in humans, 14 in human studies, the unconfounded studies that you 15 can find an increase in risk. 16 So you're -- you're left with a 17 plausible -- a synthesis of the data is that if there 18 is no data in humans that are -- expands into the 19 hundreds of thousands that there is increased risk and 20 there are hypertensives both in the exposed and 21 control group, then it is very hard to say that any 22 exposure to NDMA at levels well below what is -- 23 causes cancer in animals is playing a -- a role here. 24 So essentially that -- that's what -- what I'm saying</p>

<p>1 and that's the data and that -- that's not disputable.</p> <p>2 BY MR. DAVIS:</p> <p>3 Q. Well, I get that that's the substance</p> <p>4 of -- of your opinions as expressed in Sections III.O</p> <p>5 and VIII.</p> <p>6 My question is more just as to the</p> <p>7 structure of your report which is: Am I correct in</p> <p>8 reading Section IX as an output of the opinions that</p> <p>9 you express in Sections III.O and VII -- or in VIII?</p> <p>10 My apologies.</p> <p>11 MR. FOWLER: Objection; form.</p> <p>12 BY THE WITNESS:</p> <p>13 A. Well, here is the way I would answer that.</p> <p>14 Really, there is no inconsistencies and there is a</p> <p>15 logical sequencing of the data, how it was laid out</p> <p>16 and how it was considered to develop an aggregate</p> <p>17 opinion. So these areas of the report are -- are</p> <p>18 connected and the -- the end result is my opinion,</p> <p>19 which certainly I have no real reason to believe any</p> <p>20 different based on all that I know.</p> <p>21 BY MR. DAVIS:</p> <p>22 Q. Okay. And it's correct that you don't</p> <p>23 cite anything new in Section IX of your report,</p> <p>24 correct, aside from a filing by the plaintiffs in the</p>	<p>Page 186</p> <p>1 Q. Let me rephrase.</p> <p>2 Doctor, what is your understanding of</p> <p>3 the -- well, what -- do -- do you have an</p> <p>4 understanding whether your report applies only to</p> <p>5 Teva?</p> <p>6 MR. DAVIS: Same objections.</p> <p>7 BY THE WITNESS:</p> <p>8 A. Yes, I do. I was initially contacted in</p> <p>9 that Teva -- by Teva, but it is my understanding that</p> <p>10 I am -- my report also applies to the other defendants</p> <p>11 in the case.</p> <p>12 BY MR. FOWLER:</p> <p>13 Q. And, Doctor, directing your attention to</p> <p>14 the materials considered list, I believe it's on -- on</p> <p>15 Page 4, do you see the FDA Regulatory Documents, the</p> <p>16 Laboratory Analysis of Valsartan Products?</p> <p>17 A. Yes, I do.</p> <p>18 Q. Is that a document you reviewed in this</p> <p>19 case?</p> <p>20 A. If I reviewed it, it was cursory.</p> <p>21 Q. Do you recall whether that document</p> <p>22 contains FDA's finished dose testing for each of the</p> <p>23 manufacturing defendants in this case?</p> <p>24 A. No, I do not.</p>
<p>Page 187</p> <p>1 litigation?</p> <p>2 A. Section IX was written before the report</p> <p>3 was sent, anything that is needed to be referenced is</p> <p>4 referenced in there, so there is nothing that's come</p> <p>5 up beyond that.</p> <p>6 Q. Okay.</p> <p>7 MR. DAVIS: Okay. That's -- that's all I have.</p> <p>8 I -- I pass the witness. Thank you.</p> <p>9 THE WITNESS: Thank you.</p> <p>10 MR. FOWLER: Can -- can you all hear me if I</p> <p>11 continue to speak using the doctor's computer's</p> <p>12 microphone and rather than my own?</p> <p>13 MR. DAVIS: I can hear you.</p> <p>14 MR. FOWLER: Okay.</p> <p>15 EXAMINATION</p> <p>16 BY MR. FOWLER:</p> <p>17 Q. Dr. Flack, do you understand whether your</p> <p>18 report in this case applies only to Teva or does it</p> <p>19 apply to all of the generic manufacturing -- strike</p> <p>20 that -- or does it apply to all of the defendants in</p> <p>21 this case?</p> <p>22 MR. DAVIS: Objection to form. Objection;</p> <p>23 leading.</p> <p>24 BY MR. FOWLER:</p>	<p>Page 189</p> <p>1 Q. Based upon your review of the levels of --</p> <p>2 that FDA tested in finished doses, how did you arrive</p> <p>3 at the -- the level that you measured -- or that you</p> <p>4 utilized in reaching your opinions?</p> <p>5 MR. DAVIS: Objection; foundation. I think he</p> <p>6 just testified that he only reviewed it in a cursory</p> <p>7 manner and does not recall the -- that they tested</p> <p>8 finished dose levels. So I'm objecting to foundation</p> <p>9 there.</p> <p>10 MR. FOWLER: Well, I don't think that's --</p> <p>11 that's what he said, Counsel.</p> <p>12 BY THE WITNESS:</p> <p>13 A. So, my -- I used a -- a couple of</p> <p>14 assumptions that really augmented the exposure that</p> <p>15 someone theoretically could have had.</p> <p>16 No. 1, most of the testing was below</p> <p>17 20.1 micrograms. I used 24.1 which was -- was well</p> <p>18 above that, certainly well above the average.</p> <p>19 Two, I made the assumption that everyone</p> <p>20 got a 320-milligram pill, which is not correct because</p> <p>21 the 10-milligram -- the 160 has probably 10 micrograms</p> <p>22 in it or -- on average.</p> <p>23 So -- and the third assumption I made was</p> <p>24 that people took the pill every day at the highest</p>

<p>Page 190</p> <p>1 dose, which is also not true because many people who 2 even refill prescriptions don't take the medicine and 3 they'll stop it.</p> <p>4 So that was the -- the way that I did 5 this, and it was really teed off of the FDA and the 6 European agencies and summarizing their -- their 7 testing data, and that's how I arrived at those 8 exposures.</p> <p>9 BY MR. FOWLER:</p> <p>10 Q. Where -- where did you get the 11 20.1-microgram level that you just referenced?</p> <p>12 A. That was probably in the -- in the testing 13 data that was supplied. But I -- again, I didn't 14 spend a lot of time on it.</p> <p>15 Q. Doctor, based upon your testimony that the 16 level in valsartan is insufficient to cause cancer, 17 there would be no need to rule out NDMA as a cause of 18 cancer in your hypertension patients, correct?</p> <p>19 A. What I don't know --</p> <p>20 MR. DAVIS: Objection; leading. Sorry.</p> <p>21 BY THE WITNESS:</p> <p>22 A. What I repeatedly said is I do not know 23 how to rule out NDMA as a cause of cancer in an 24 individual patient when you can't find it in hundreds</p>	<p>Page 192</p> <p>1 mark what has been previously provided to -- to 2 counsel. I want to mark your supplemental list of 3 materials considered as the next exhibit. I believe 4 it's possibly 11.</p> <p>5 MR. FOWLER: Whatever the next exhibit is, Madam 6 Court Reporter.</p> <p>7 MR. DAVIS: Steve, I've -- I've marked ours as 8 Plaintiffs, Plaintiff-X -- Flack, so --</p> <p>9 MR. FOWLER: That's fine.</p> <p>10 MR. DAVIS: -- you probably don't want to mark 11 that as a plaintiff's exhibit?</p> <p>12 MR. FOWLER: I'll mark it as Flack what is the 13 next number. I don't mind using your nomenclature 14 just so they are all together, Counsel.</p> <p>15 MR. DAVIS: That's fine. That's fine.</p> <p>16 MR. FOWLER: Would it be 12?</p> <p>17 MR. DAVIS: It would be -- let's see.</p> <p>18 MR. FOWLER: Madam Court Reporter, you can 19 easily tell us that.</p> <p>20 MR. DAVIS: It would be 12.</p> <p>21 MR. FOWLER: Okay. Thank you.</p> <p>22 (WHEREUPON, a certain document was 23 marked Plaintiff-Flack Deposition 24 Exhibit No. 12, for identification,</p>
<p>Page 191</p> <p>1 of thousands of patients. So I -- I don't know how to 2 do it, and I'm a pretty good doctor.</p> <p>3 BY MR. FOWLER:</p> <p>4 Q. Doctor, if FDA's finished dose testing of 5 all of the defendant manufacturers' finished dose 6 products was -- with -- with the exception of one was 7 below 20.1, would you need to know each of those lower 8 levels to render your opinion?</p> <p>9 MR. DAVIS: Objection; foundation.</p> <p>10 BY THE WITNESS:</p> <p>11 A. So in -- I went well above the highest 12 level in the assumptions I made about exposure.</p> <p>13 BY MR. FOWLER:</p> <p>14 Q. And does that opinion with regard to the 15 exposure level, would you apply that to each of the 16 defendants in this case?</p> <p>17 MR. DAVIS: Objection.</p> <p>18 MS. KAPKE: Was there an answer to that 19 question? I'm sorry. I didn't hear it.</p> <p>20 BY THE WITNESS:</p> <p>21 A. Yes.</p> <p>22 MS. KAPKE: Thanks.</p> <p>23 BY MR. FOWLER:</p> <p>24 Q. A little housekeeping. I -- I want to</p>	<p>Page 193</p> <p>1 as of 09/28/2021.)</p> <p>2 BY MR. FOWLER:</p> <p>3 Q. As -- as Plaintiffs' Flack Exhibit 12, I'm 4 putting before you the supplemental reliance list, 5 Doctor.</p> <p>6 Have you seen this document before?</p> <p>7 A. Yes, I have.</p> <p>8 MR. FOWLER: And I also want to mark a -- a 9 flash drive which contains all of your reliance 10 material which has been provided to -- to counsel, but 11 I'd like to mark this as -- as Plaintiff-Flack 13.</p> <p>12 And, Madam Court Reporter, we'll -- we'll 13 overnight the flash drive to you, is that all right, 14 we'll put it in an envelope?</p> <p>15 THE COURT REPORTER: Yes.</p> <p>16 MR. FOWLER: Okay. So we'll put that there.</p> <p>17 (WHEREUPON, a certain document was 18 marked Plaintiff-Flack Deposition 19 Exhibit No. 13, for identification, 20 as of 09/28/2021.)</p> <p>21 MR. FOWLER: Madam Reporter, we want to 22 introduce an exhibit through the -- through the chat 23 since we obviously don't have the link, but we're 24 having difficulty.</p>

<p>1 Can we -- do you understand why we may not 2 be able to introduce that in the chat room?</p> <p>3 THE COURT REPORTER: No.</p> <p>4 MR. FOWLER: Or how we can upload this exhibit? 5 It is just not dropping in.</p> <p>6 MR. DAVIS: Hey, Steve, while she is looking 7 into that, was this supplemental list of materials 8 that you've marked as 12, was that provided to me?</p> <p>9 MR. FOWLER: It was. Counsel, it was in the -- 10 the 48 hours before set of documents that we provided.</p> <p>11 And -- and, Counsel, I can tell you that 12 it goes to Page 20 -- it goes to Page 22. It doesn't 13 say supplemental. That's our -- our bad, but it -- 14 you'll know that it is the supplemental list because 15 it goes to -- to 22 as opposed to I think 20 on the -- 16 the previous.</p> <p>17 MR. DAVIS: Okay. I'm going to reserve my 18 rights on that until I can confirm that that was 19 actually provided to me. I'm not saying that it 20 wasn't, but I -- I don't have it, so.</p> <p>21 MR. FOWLER: Sure, sure. I understand.</p> <p>22 Can -- Madam Reporter, can we e-mail you 23 the exhibit we want to -- to introduce? How can we -- 24 we can present this? Because typically we are able to</p>	<p>Page 194</p> <p>1 MR. DAVIS: And, Steve, before you continue, let 2 me just state a continuing objection here because 3 I'm -- I'm not sure I received this supplemental list 4 of materials, having just gone through my e-mails. 5 So I'm just going to as a matter of 6 caution put a continuing objection on the record on 7 that.</p> <p>8 MR. FOWLER: Okay. I'm not -- I'm not asking 9 about it. All I did is mark it, Counsel. I'm not 10 asking any other questions other than you've seen it 11 and it's marked. None of these -- this is -- I've 12 moved past that.</p> <p>13 MR. DAVIS: Okay.</p> <p>14 MR. FOWLER: So you -- your objection is noted 15 and I understand if -- if there is some -- I 16 understand your objection and your reservation.</p> <p>17 BY MR. FOWLER:</p> <p>18 Q. Counsel (sic), do you recall a -- the 19 questions about the -- the research grants that you 20 have been awarded over the years in the course of your 21 professional career?</p> <p>22 A. Yes, I do.</p> <p>23 Q. With regard to the money that -- that 24 is -- is the grant, if you will, who gets that money?</p>
<p>Page 195</p> <p>1 drop it into the chat and it is not happening.</p> <p>2 THE COURT REPORTER: I would suggest that you 3 e-mail it to Mr. Davis and he upload it.</p> <p>4 MR. FOWLER: Okay. We'll do that. We'll do 5 that. And just lift that up so it's ready and I'll 6 tell you when to send it, please.</p> <p>7 BY MR. FOWLER:</p> <p>8 Q. Doctor, early on in this deposition, you 9 were asked whether any category of documents relied 10 upon in reaching your opinion that's not listed.</p> <p>11 Do you recall that, that question?</p> <p>12 A. Yes, I do.</p> <p>13 Q. Is there any other source of information 14 that you relied upon in forming your opinions that was 15 not listed?</p> <p>16 A. Well, I have decades of experience. Even 17 after my formal residency training, I've learned more 18 medicine, more epidemiology, since I finished my 19 medical training and my epidemiology training through 20 the school of hard knocks application, going through 21 the peer review and grant process. So that would be 22 a -- a source of knowledge that would really buttress 23 any of the specific material listed in -- in the 24 documents that were provided to me or I pulled.</p>	<p>Page 197</p> <p>1 A. So the vast majority of the money that 2 comes in for a grant goes to support space rental, 3 personnel needed to -- and professionals, dieticians, 4 nurses, medical assistants, receptionists, secretaries 5 to actually do the work. The school always gets a 6 cut, and there are indirect costs. The investigators, 7 particularly in an industry-sponsored grant, really 8 get a small sliver of that, and typically what happens 9 is it -- it goes into your salary to support your 10 existing salary and is not added on top of it. So 11 it's a level of support that is there, but only a -- a 12 few percentage points of the overall total grant go -- 13 come directly to you as the investigator.</p> <p>14 Q. Doctor, directing your attention to 15 Page 25 of your report, in that paragraph under 16 Section O, Epidemiology of Hypertension and Cancer, do 17 you recall being asked questions about the -- the 18 second sentence in that paragraph that begins "BP 19 level"?</p> <p>20 A. Yes, I do.</p> <p>21 Q. Now, is the actual -- hypertension is 22 actually the -- the blood pressure level. Have I got 23 that part right?</p> <p>24 A. The hypertension initially diagnosed is</p>

<p>1 the blood pressure level, but even if your blood 2 pressure is 110 over 70, if you are on 3 antihypertensive drugs you have hypertension despite 4 the fact that your pressure now is a little more on 5 those drugs.</p> <p>6 Q. And my -- my question with regard to the 7 sentence when you referred to kidney cancer, you 8 referred -- is -- is that specific to the blood 9 pressure level as -- I'm going to stop there.</p> <p>10 A. So kidney cancer --</p> <p>11 MR. DAVIS: Objection.</p> <p>12 BY THE WITNESS:</p> <p>13 A. -- unlike a number of cancers appears to 14 show a risk gradient that's in direct relation to the 15 level of blood pressure. That's not true in many 16 other cancers, but for some reason it is in kidney 17 cancer.</p> <p>18 BY MR. FOWLER:</p> <p>19 Q. When -- when you expressed your opinion 20 about the risk of cancer in hypertension patients, 21 other than the actual BP level, what else were you 22 referring to there?</p> <p>23 A. So there -- there are a number of 24 potential explanations for high levels of cancer in</p>	<p>Page 198</p> <p>1 state exactly what it is, what -- what question it was 2 that you were asked to answer in this case, I should 3 say?</p> <p>4 A. Well, I can state it again. I -- I was 5 asked in hypertensive patients to make a general 6 causation determination as to whether the level of 7 exposure to valsartan containing NDMA caused cancer, 8 and that -- that's what I was asked to do.</p> <p>9 Q. And when you say "caused cancer," are you 10 speaking of causing cancer or are you speaking of 11 increased -- any increased risk?</p> <p>12 A. What I'm speaking of is in human studies, 13 basically the best evidence that we have, is there 14 evidence that valsartan in the amounts that were out 15 there for the duration of time potentially in pills 16 caused cancer.</p> <p>17 Q. And did you assess that risk against the 18 patient population that -- that you've pres -- of the 19 type that you've prescribed valsartan to?</p> <p>20 A. Well, in these studies the -- you've got 21 people with hypertension, one, valsartan, you have 22 people who are not on valsartan, and so you've got 23 a -- a reasonably comparable group to -- to look at. 24 And in those studies there is virtually no indication</p>
<p>Page 199</p> <p>1 patients with hypertension, and a lot of it has to do 2 with comorbidities that are listed, some of which 3 intersect on the same cancers, and diabetes, obesity, 4 levels of physical activity, dietary intake, a variety 5 of things that are more common in hypertensive 6 patients than in non-hypertensive patients that have 7 been linked to cancer themselves.</p> <p>8 Q. And, Doctor, for your hypertensive patient 9 population, as a matter of your routine following of 10 those patients, are they subject to ongoing health 11 assessments and surveillance?</p> <p>12 MR. DAVIS: And I'm going to object to the form. 13 But, also, Steve, you've accidentally turned your 14 camera off.</p> <p>15 MR. FOWLER: Sorry about that.</p> <p>16 BY THE WITNESS:</p> <p>17 A. So hypertensive patients, if you look at 18 ACC/AHA guidelines, European guidelines and -- and 19 what we do in practice, it -- you basically -- they -- 20 they are surveilled like non-hypertensive patients for 21 other non-cardiovascular conditions.</p> <p>22 BY MR. FOWLER:</p> <p>23 Q. Okay. And, Doctor, bear with me here, 24 can -- have -- have you had an opportunity to -- to</p>	<p>Page 201</p> <p>1 that exposure at this level for this duration causes 2 cancer.</p> <p>3 MR. FOWLER: Counsel, we are sending you an 4 article that we are going to mark as 5 Plaintiffs-Flack 14. You should be receiving it 6 imminently.</p> <p>7 And for the record, this article is 8 published in the Pharmacology & Therapeutics Journal. 9 It's called "Carcinogenesis: Failure of resolution of 10 inflammation?" by Dr. Anna Fishbein, Bruce Hammock, 11 Charles Serhan, and Dipak Panigrahy.</p> <p>12 Tell me when you have it, Counsel, and 13 if -- if you wouldn't mind, please, loading that up.</p> <p>14 MR. DAVIS: Okay. I haven't received it yet.</p> <p>15 MR. FOWLER: Yeah, just give it a beat. It 16 will -- it will pop up.</p> <p>17 Okay. I'll direct it.</p> <p>18 MR. DAVIS: Okay. I've -- I've got it. So 19 what -- what are you asking me to do, Counsel?</p> <p>20 MR. FOWLER: If you can screen share the last 21 page, please.</p> <p>22 MR. DAVIS: Okay. Are you going to be marking 23 this as an exhibit?</p> <p>24 MR. FOWLER: Yes. That's Plaintiffs-Flack 14.</p>

<p>1 (WHEREUPON, a certain document was 2 marked Plaintiff-Flack Deposition 3 Exhibit No. 14, for identification, 4 as of 09/28/2021.)</p> <p>5 MR. DAVIS: Okay. I'm going to, again, reserve 6 rights. Me marking it as an exhibit, I mean, 7 Plaintiffs' something doesn't mean I'm okay with it.</p> <p>8 MR. FOWLER: I totally understand. I appreciate 9 your accommodation.</p> <p>10 MR. DAVIS: It is an .eml link as opposed to a 11 PDF. Let me see if it still --</p> <p>12 MR. FOWLER: No, we sent a PDF. We believe we 13 sent it as a PDF. We opened it as a PDF.</p> <p>14 And -- and, you know, it is -- it is 15 not -- it is not essential if you can't pull it up. I 16 can -- I only have a single question.</p> <p>17 MR. DAVIS: So I'm going to -- I'm marking 18 this -- I'm going to mark it as 13 (sic). I don't 19 have the supplemental invoice that you've asked to be 20 marked as 12 (sic), so that one is going to be skipped 21 for the record. So I'm renaming this 13 (sic) for the 22 record.</p> <p>23 MR. FOWLER: Thirteen was the flash drive.</p> <p>24 MR. DAVIS: Oh, all right. Sorry. It's</p>	<p>Page 202</p> <p>1 If you -- if you as an editor of a journal 2 received an article co-written by an author who while 3 writing it had received over half a million dollars 4 from counsel for plaintiffs in a litigation directly 5 on the same issue being written about, would you as an 6 editor expect the conflicts of interest to disclose 7 that? And I'll just stop there.</p> <p>8 MR. DAVIS: Objection; foundation. I don't 9 think you've even established that the witness has 10 reviewed this article.</p> <p>11 MR. FOWLER: That's okay.</p> <p>12 MR. DAVIS: I meant objection to the --</p> <p>13 BY THE WITNESS:</p> <p>14 A. So my understanding of the question is if 15 I'm a journal editor and I'm -- and I have -- I 16 received an article and someone has either first 17 authored, last authored or middle authored the article 18 and they receive half a million dollars from a 19 pharmaceutical company or other entity that they are 20 actually providing expert opinions for, there -- there 21 is just no way that that should not be disclosed. 22 That would be expected to be disclosed.</p> <p>23 As an editor, you are at the mercy by and 24 large of, one, what people report to you, unless you</p>
<p>Page 203</p> <p>1 already -- it's already introduced. We'll have to 2 clear that up later.</p> <p>3 MR. FOWLER: That's fine, Counsel. Thank you.</p> <p>4 So I should -- I take it if you are not 5 able to share it, I'll just ask my questions, is that 6 right?</p> <p>7 MR. DAVIS: I can -- I can share a PDF, but when 8 it loaded into the Golkow remote thing, it loaded as 9 an .eml, so I'm not sure what that means, but I've -- 10 I've got a PDF I can share here.</p> <p>11 MR. FOWLER: Okay. So at least you can see it, 12 Counsel. That's fine.</p> <p>13 MR. DAVIS: Okay. That's fine.</p> <p>14 BY MR. FOWLER:</p> <p>15 Q. Let -- let me see it and go to the last 16 page. Actually, it's -- it's the -- the declar -- 17 the dec -- well, the declaration of interest. It's on 18 PDF Page 24 of 37. And I would represent, Doctor -- 19 well, let me ask it this way.</p> <p>20 Doctor, as counsel said during your 21 questioning, he asked you to put your shoes -- put 22 yourself in the shoes of an editor of a journal. So 23 I'd like you to put those shoes back on, and I want to 24 ask you this question.</p>	<p>Page 204</p> <p>1 ever some very specific information that -- that you 2 are aware of. So it's really kind of an honor system, 3 but there -- there is no good explanation for why you 4 would have received that amount of money from an 5 entity while you are working on this litigation and 6 then write a scientific article that is in parallel 7 and essentially the same subject and not include that 8 as a potential conflict.</p> <p>9 BY MR. FOWLER:</p> <p>10 Q. And -- and you recall being shown an 11 article that you drafted where in the Conflicts of 12 Interest you disclosed being a speaker for a number of 13 pharmaceutical companies.</p> <p>14 Do you recall that?</p> <p>15 MR. DAVIS: I just meant to get an objection on 16 the record there before you move on that I object to 17 that as proffering an expert opinion on -- on 18 something the -- the witness is not designated to -- 19 to -- as an expert on.</p> <p>20 THE WITNESS: I actually am an expert. I'm a 21 general editor.</p> <p>22 MR. FOWLER: Objection to the --</p> <p>23 MR. DAVIS: You haven't been proffered as an 24 expert though, Dr. Flack.</p>

<p>1 MR. FOWLER: Well, we'll have to talk about 2 that.</p> <p>3 MR. DAVIS: Okay. Okay.</p> <p>4 BY MR. FOWLER:</p> <p>5 Q. Counsel (sic), do you recall being shown 6 your disclosure in the conflicts of interest in the 7 article that you wrote?</p> <p>8 A. Yes, I do.</p> <p>9 Q. And why -- can you explain as a journal 10 editor why it's important to have that section on the 11 conflicts of interest?</p> <p>12 A. The -- the real issue as a journal editor 13 that -- that you are trying to steer away from is the 14 lack of transparency. And so what you do is you ask 15 authors to disclose their conflicts on ownership, 16 remuneration, and certainly ownership, remuneration 17 instruments variables, payment that relate to or even 18 potentially could be related to the subject matter 19 that they are writing on.</p> <p>20 Everything that is listed as a potential 21 conflict, it's not sitting there saying you're -- 22 you're creating some kind of damning of the -- of the 23 author. You are just simply saying, here are the 24 author's potential conflicts and it's an exercise in</p>	<p>Page 206</p> <p>1 documents and information that was important -- 2 important or relevant to your opinions?</p> <p>3 A. Yeah, I looked over documents and -- and 4 all and a lot of the documents simply were not 5 directly relevant to me or sometimes they contained 6 information that I could pull for -- from elsewhere, 7 such as what the FDA did, for example, with NDMA in -- 8 in their -- in their testing.</p> <p>9 Q. Do you believe you needed any information 10 or depositions or documents from any of the other 11 manufacturers in order to form your opinions in this 12 case?</p> <p>13 A. No. I had plenty of information to make 14 the case that -- that I made about the level of 15 exposure and also in relationship to animal models and 16 what we see in humans and then look at the human 17 studies.</p> <p>18 Q. Has counsel today shown you any document 19 from any other manufacturer reflecting the level of 20 NDMA in valsartan higher than the level that you 21 assumed in doing your calculations?</p> <p>22 MR. DAVIS: Objection; leading.</p> <p>23 BY THE WITNESS:</p> <p>24 A. I -- I haven't seen in any FDA material</p>
<p>Page 207</p> <p>1 transparency that you are engaging in.</p> <p>2 When you don't have that and you've got a 3 sizeable conflict, that's just not where you want to 4 be and that's not the expectation that any credible 5 journal would have.</p> <p>6 MR. DAVIS: Steve, you are off camera again.</p> <p>7 MR. FOWLER: Oh, I don't know what is happening 8 there. Hold on. I'm not even touching the thing, but 9 okay.</p> <p>10 BY MR. FOWLER:</p> <p>11 Q. Doctor, I'm asking you about the materials 12 considered list using what counsel had marked as 13 exhibit, I think it was 3.</p> <p>14 Did -- did you have access to all of the 15 documents and information contained on Exhibit 3?</p> <p>16 MR. DAVIS: Exhibit, for the record, that's 17 Exhibit 10 is the materials considered.</p> <p>18 MR. FOWLER: Okay. Thank you, Counsel.</p> <p>19 BY MR. FOWLER:</p> <p>20 Q. On Exhibit 10 that counsel marked, did you 21 have access to all of that, those documents that were 22 provided to you?</p> <p>23 A. I had access to them.</p> <p>24 Q. Were you able to identify or select those</p>	<p>Page 209</p> <p>1 nor in any document produced today a level as high as 2 what I used in my calculations.</p> <p>3 MR. FOWLER: All right. Thank you, Doctor. No 4 further questions.</p> <p>5 FURTHER EXAMINATION</p> <p>6 BY MR. DAVIS:</p> <p>7 Q. Okay. Doctor, I just have a few 8 follow-ups. Let's -- let's start with this Fishbein 9 article that's in the Journal of Pharmacology & 10 Therapeutics. I believe that it's marked as maybe 11 Exhibit 13 (sic), but I'm not positive about that.</p> <p>12 Had you reviewed this article prior to 13 being shown it today?</p> <p>14 Doctor, did you -- did you get the 15 question or are we breaking up?</p> <p>16 A. No, you are not breaking up. I'm just 17 looking.</p> <p>18 No.</p> <p>19 Q. Okay. Are you familiar that many journals 20 keep their own rules as to what needs to be disclosed 21 as to conflicts of interest?</p> <p>22 MR. FOWLER: Objection; form, foundation.</p> <p>23 BY THE WITNESS:</p> <p>24 A. I've been an associate editor of three</p>

<p>Page 210</p> <p>1 journals and while the -- the disclosures may vary 2 some, there -- there would never be an instance where 3 you would get a half a million dollars on a subject 4 that you wrote an article for from an entity and then 5 not disclose that payment. There is -- there is no 6 journal around that would do that. I'm also on the 7 American College of Physician Board of Regents, I can 8 tell you extensively what the Journal of the Annals of 9 Internal Medicine does, and if something like that 10 came to knowledge there, it -- Christine Lang would 11 bring it to the board and -- and all and it would not 12 be something that was just overlooked.</p> <p>13 BY MR. DAVIS:</p> <p>14 Q. Have you specifically reviewed the 15 conflicts of interest disclosure rules that are 16 maintained by the Journal of Pharmacology & 17 Therapeutics where this article was published?</p> <p>18 A. I have not specifically reviewed those, 19 but I will again state that there is no ethical 20 journal committed to transparency that would allow a 21 half a million dollar payment on a subject that you 22 are writing an article for not to be disclosed.</p> <p>23 Q. But that's without having actually 24 reviewed the disclosure rules by this particular</p>	<p>Page 212</p> <p>1 MR. FOWLER: Well, objection to the colloquy for 2 the 15th time today.</p> <p>3 BY MR. DAVIS:</p> <p>4 Q. When did you learn that your report would 5 not just apply to Teva but to other defendants?</p> <p>6 MR. FOWLER: Objection; form, to the extent you 7 are calling for attorney/client privilege.</p> <p>8 BY MR. DAVIS:</p> <p>9 Q. I'm asking a --</p> <p>10 A. Sometime --</p> <p>11 Q. -- a when, not a --</p> <p>12 A. Sometime after my engagement with Teva.</p> <p>13 Q. So that could include any time from your 14 engagement up through today?</p> <p>15 MR. FOWLER: Objection; form.</p> <p>16 BY THE WITNESS:</p> <p>17 A. Oh, I knew well before today that it's 18 sometime, and I don't remember the exact date, but 19 I -- I understood that.</p> <p>20 BY MR. DAVIS:</p> <p>21 Q. You -- you understood that after meeting 22 with 20 minutes with your counsel to discuss your 23 redirect?</p> <p>24 MR. FOWLER: Objection; form, argumentative,</p>
<p>Page 211</p> <p>1 journal, correct?</p> <p>2 A. What you are really trying to minimize is 3 the fact that I have been an associate editor for 4 three journals and have written a couple hundred 5 publications and am intimately familiar with Annals of 6 Internal Medicine which is one of the best journals of 7 the world because I sit on the American College of 8 Physicians board, and there is no wiggle room in 9 differences in how journals require disclosure that 10 would excuse that, none.</p> <p>11 Q. But that's speculation because you have -- 12 as you have testified, you haven't actually reviewed 13 this journal's rules, which are what govern 14 disclosures in this journal, correct?</p> <p>15 A. So my speculation based on my experience 16 is -- is pretty sound and there -- there is -- there 17 is not a journal, and I doubt you reviewed it either, 18 there is not a journal that I have ever had any 19 association with, and I've been to conferences about 20 this, I have listened to editorial discussions, this 21 violates the spirit of transparency and disclosure, 22 and trying to defend this is shameful.</p> <p>23 Q. Thank you for that commentary. I'm going 24 to for the second time move to strike something today.</p>	<p>Page 213</p> <p>1 mischaracterizing.</p> <p>2 BY THE WITNESS:</p> <p>3 A. I don't think that's what I said, and you 4 are deliberately twisting and actually distorting what 5 I said. That is not what I said.</p> <p>6 BY MR. DAVIS:</p> <p>7 Q. You mentioned that there appears to be a 8 linkage for kidney -- this is Section III.O of your 9 report, you were asked some questions, and I believe 10 gave an answer indicating that the linkage between 11 kidney cancer increased as blood pressure levels 12 increased.</p> <p>13 Is that -- was that your testimony?</p> <p>14 MR. FOWLER: Objection; form, mischaracterizing.</p> <p>15 BY THE WITNESS:</p> <p>16 A. There is a statement in the paper that 17 says unlike many cancers, something to that effect, 18 there is a direct relationship between the risk of 19 kidney cancer and blood pressure level.</p> <p>20 BY MR. DAVIS:</p> <p>21 Q. In your practice of treating 22 hypertensives, are your uncontrolled patients under a 23 greater degree of medical surveillance than your 24 controlled hypertension patients?</p>

<p>1 A. Our practice in -- and, again, it follows 2 the evidence and -- and recommendations which are 3 based on evidence to the degree we agree with it, at 4 the end of the day your patients are under 5 surveillance for their general health, and if we have 6 hypertensive patients who are controlled or 7 uncontrolled, we -- we really have a fairly similar 8 way of -- of surveilling them and their health risk 9 are both cardiovascular and non-cardiovascular. 10 Q. So is the answer to my -- my question 11 that, yes, your uncontrolled hypertension patients are 12 indeed under a greater degree of medical surveillance 13 than your controlled ones? 14 MR. FOWLER: Objection; form. 15 BY THE WITNESS: 16 A. Actually, there is nothing in the answer I 17 just gave you that would lead you to say that. So my 18 hypertensive patients who are controlled and 19 uncontrolled essentially get the same surveillance. 20 BY MR. DAVIS: 21 Q. You don't -- you don't make a point to 22 schedule more diagnostic tests, more appointments with 23 patients who are not under control in terms of their 24 blood pressure levels than you do your patients that</p>	<p>1 So I'm a pretty good doctor, and I don't 2 do stuff like that just to practice defensive 3 medicine. 4 Q. But, Doctor, I'm not asking you about 5 kidney cancer right now. I'm asking you about how you 6 treat your uncontrolled hypertension patients versus 7 your controlled ones. 8 And my question is: To a general -- as a 9 general principle, are you placing your uncontrolled 10 hypertension patients under a greater degree of 11 medical surveillance than you are someone who is on 12 therapy and with -- has blood pressure levels within 13 acceptable levels? 14 A. Counselor, I have answered that question 15 now a couple of times. Patients often switch back and 16 forth between controlled and uncontrolled. And I've 17 already answered that question and told you no. 18 Q. Okay. The list of supplemental materials 19 that you reviewed that I don't have, so, you know, I'm 20 going to reserve all rights to raise more questions 21 about that at a certain point if -- if it's true that 22 that wasn't sent to me, how -- what's -- what's 23 generally on that list? Can you -- can you tell me 24 what's on the list?</p>
<p>1 are within acceptable ranges? 2 A. So let me explain to you what you are 3 asking and why you are barking up the wrong tree. 4 No. 1, when you start looking and doing a 5 bunch of testing for something that is very low 6 prevalence, it's a fact that most of the positive 7 tests you get are going to be false positives because 8 the prevalence of the disease is low. That's the 9 problem you run into screening for pheochromocytoma. 10 And that is a problem that you are going to run into 11 for screening for kidney cancer. If I took all of my 12 uncontrolled patients and ordered CAT scans on them, 13 looking at their kidneys or did invasive testing and 14 all, I would be a wasteful doctor, I would not only be 15 wasteful, but I would be finding things that people 16 would be following up on and cause harm to the 17 patient. So no, on something very low prevalence, 18 just because there is an increased risk, it doesn't 19 mean that because it's probably at the bottom of the 20 potential things you are going to find that you go and 21 do a bunch of testing. And that's based on solid 22 epidemiologic principles. You can't really start 23 looking for low prevalence diseases because most of 24 your positive tests are going to be false positives.</p>	<p>1 Page 215 2 MR. FOWLER: Objection; form, super broad and 3 the list speaks for itself. 4 MR. DAVIS: Well, I have no choice, Steve, I 5 don't have the document, so I'm going to start with 6 some general questions. 6 BY MR. DAVIS: 7 Q. Dr. Flack, do you know generally what's -- 8 what's on that list of materials considered that's 9 supplemental? 10 MR. FOWLER: That's a different question. 11 THE WITNESS: What's this? 12 MR. FOWLER: That's not the supplemental. 13 THE WITNESS: Is this the stuff that was sent 14 yesterday? 15 MR. FOWLER: That's -- that's -- that's the 16 original. 17 THE WITNESS: Was this the stuff that was sent 18 yesterday? 19 MR. FOWLER: In part. I -- I don't -- I can't 20 help you out, but it -- I mean, the differences speak 21 for themselves. 22 BY THE WITNESS: 23 A. It is probably some stuff you got with 24 regards to sheets that were marked up for me and --</p>

<p>1 and all. That's what I -- I know about.</p> <p>2 MR. DAVIS: Okay. Well, okay. Since it appears</p> <p>3 I can't get any specific answers on it, I'm going to</p> <p>4 reserve my rights on that.</p> <p>5 BY MR. DAVIS:</p> <p>6 Q. Doctor, did you -- did you write an</p> <p>7 editorial recently suggesting that ARBs can help with</p> <p>8 COVID in some way?</p> <p>9 A. That would be a mischaracterization of the</p> <p>10 editorial, because we don't know about that and there</p> <p>11 are people who have been on both sides of this fence</p> <p>12 who think that, you know, it could be harmful,</p> <p>13 potentially helpful, and we just don't have good -- a</p> <p>14 good understanding of that.</p> <p>15 Q. But you're familiar with the editorial I'm</p> <p>16 talking about?</p> <p>17 A. Correct.</p> <p>18 Q. Okay. Why was that not disclosed on your</p> <p>19 CV?</p> <p>20 A. My -- my disclosure for the American</p> <p>21 Journal of Hypertension certainly has been disclosed</p> <p>22 and if the editorial is not on my CV, it's just an</p> <p>23 oversight because it should be on my CV.</p> <p>24 Q. Did you disclose the work you've done in</p>	<p>1 to me today.</p> <p>2 MR. FOWLER: No objection.</p> <p>3 (WHEREUPON, a certain document was</p> <p>4 marked Plaintiff-Flack Deposition</p> <p>5 Exhibit No. 15, for identification,</p> <p>6 as of 09/28/2021.)</p> <p>7 MR. DAVIS: That's marked as Plaintiff-Flack 14</p> <p>8 (sic).</p> <p>9 MR. FOWLER: I think it would have to be 15,</p> <p>10 right?</p> <p>11 MR. DAVIS: Or, yeah, I guess we'll -- after</p> <p>12 this is over we can have a discussion with the court</p> <p>13 reporter.</p> <p>14 MR. FOWLER: Sure.</p> <p>15 BY MR. DAVIS:</p> <p>16 Q. Let me publish real fast -- I'm publishing</p> <p>17 what at present is marked as Plaintiffs-Exhibit 14</p> <p>18 (sic).</p> <p>19 This is your supplemental invoice that</p> <p>20 documents work through September 7th, between</p> <p>21 July 21st and September 7th, correct?</p> <p>22 A. Correct.</p> <p>23 Q. And do you see that the amount due there</p> <p>24 is \$7800?</p>
<p>1 this case that you contend would be a conflict of</p> <p>2 interest worthy of disclosure in that editorial?</p> <p>3 MR. FOWLER: Objection; form.</p> <p>4 BY THE WITNESS:</p> <p>5 A. Well, Counselor, you haven't done your</p> <p>6 homework. The article -- the editorial that I wrote</p> <p>7 with Ernesto Shiff, one of the other editorial</p> <p>8 coauthors, well annotated any work that I -- I did</p> <p>9 here. So it's really hard for me to preemptively list</p> <p>10 a disclosure when you are talking about a timeframe</p> <p>11 that began -- was well before I ever was engaged on</p> <p>12 this.</p> <p>13 BY MR. DAVIS:</p> <p>14 Q. Okay. But nonetheless, that -- that</p> <p>15 editorial is not disclosed in your CV, correct?</p> <p>16 MR. FOWLER: Objection; form, disclosed.</p> <p>17 BY THE WITNESS:</p> <p>18 A. If the editorial is not on my CV,</p> <p>19 certainly it is just an oversight. It is in the</p> <p>20 public record and really has -- has no direct bearing</p> <p>21 on this case.</p> <p>22 BY MR. DAVIS:</p> <p>23 Q. Just one final housekeeping matter. I'm</p> <p>24 going to mark the supplemental invoice that was sent</p>	<p>1 A. For the amount of work I did, correct.</p> <p>2 Q. And do you see that the description of</p> <p>3 services is almost verbatim the description of</p> <p>4 services from your first invoice?</p> <p>5 A. It is a continuation of what I've been</p> <p>6 doing.</p> <p>7 Q. Okay.</p> <p>8 A. So it should be.</p> <p>9 Q. How many hours would you estimate between</p> <p>10 September 7th and today that you have accumulated?</p> <p>11 A. Probably about 14 or 15.</p> <p>12 Q. Was your method in this -- for these</p> <p>13 13 hours that are listed here, was your method of</p> <p>14 tabulating them the same way as it was in the first</p> <p>15 invoice, which is namely you testified your memory and</p> <p>16 maybe some sticky notes?</p> <p>17 A. I didn't testify memory and maybe sticky</p> <p>18 notes. I testified my memory and sticky notes, and</p> <p>19 there has been no change in how I -- I count the</p> <p>20 hours.</p> <p>21 Q. Okay. And do you have those sticky notes?</p> <p>22 A. No, I do not.</p> <p>23 Q. In your possession?</p> <p>24 A. No.</p>

<p style="text-align: right;">Page 222</p> <p>1 Q. Okay. What -- what happened to them? 2 A. I don't know. 3 Q. You threw them out? 4 A. Maybe somebody took them off of my 5 computer, I don't know, maybe the janitor ate them. I 6 don't have them. 7 Q. Did you look for them? 8 A. Why would I look for them? 9 Q. Because they are responsive to the notice 10 we served on you.</p> <p>11 MR. FOWLER: Objection; form, argumentative. 12 BY THE WITNESS:</p> <p>13 A. I told you how I tabulated. They may be 14 on my computer, they may be not and -- and all, but I 15 have it in my head, because I haven't really done that 16 much and I kept a running -- a running tabulation on 17 it, so.</p> <p>18 MR. DAVIS: Okay. I'm going to formally request 19 that those notes be searched for, Counsel. They 20 are -- they are responsive, and it's -- it doesn't 21 appear that he is aware of whether they exist or not, 22 so I'm -- I'm going to request that those be searched 23 for. And that -- that concludes my I suppose recross, 24 Doctor. Thank you.</p>	<p style="text-align: right;">Page 224</p> <p>1 REPORTER'S CERTIFICATE 2 3 I, JULIANA F. ZAJICEK, a Registered 4 Professional Reporter and Certified Shorthand 5 Reporter, do hereby certify that prior to the 6 commencement of the examination of the witness herein, 7 the witness was duly remotely sworn by me to testify 8 to the truth, the whole truth and nothing but the 9 truth.</p> <p>10 I DO FURTHER CERTIFY that the foregoing is 11 a verbatim transcript of the testimony as taken 12 stenographically by me at the time, place and on the 13 date hereinbefore set forth, to the best of my 14 availability.</p> <p>15 I DO FURTHER CERTIFY that I am neither a 16 relative nor employee nor attorney nor counsel of any 17 of the parties to this action, and that I am neither a 18 relative nor employee of such attorney or counsel, and 19 that I am not interested directly or indirectly in the 20 outcome of this action.</p> <p>21 IN WITNESS WHEREOF, I do hereunto set my 22 hand on this 4th day of October, 2021.</p> <p>23</p> <p>24 JULIANA F. ZAJICEK, Certified Reporter</p>
<p style="text-align: right;">Page 223</p> <p>1 MR. FOWLER: Thank you, Counsel. Nothing 2 further. I think that's a wrap. Thanks everybody. 3 MR. DAVIS: Thank you. 4 THE VIDEOGRAPHER: The time is 3:14 p m. We are 5 off the record. 6 --- 7 Thereupon, at 3:14 p.m., on Tuesday, 8 September 28, 2021, the deposition was concluded. 9 --- 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24</p>	<p style="text-align: right;">Page 225</p> <p>1 DEPOSITION ERRATA SHEET 2 3 4 Case Caption: In Re: Valsartan, Losartan, and 5 Irbesartan Products Liability Litigation 6 7 DECLARATION UNDER PENALTY OF PERJURY 8 9 I declare under penalty of perjury that I 10 have read the entire transcript of my Deposition taken 11 in the captioned matter or the same has been read to 12 me, and the same is true and accurate, save and except 13 for changes and/or corrections, if any, as indicated 14 by me on the DEPOSITION ERRATA SHEET hereof, with the 15 understanding that I offer these changes as if still 16 under oath. 17 18 JOHN M. FLACK, MD, MPH, FAHA, MACP, FASH 19 20 SUBSCRIBED AND SWORN TO 21 before me this day 22 of , A.D. 20__. 23 24 Notary Public</p>

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Errata Sheet

September 28, 2021

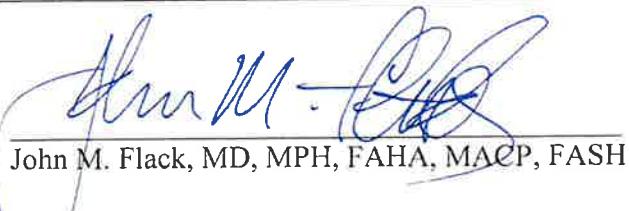
Deposition Transcript – John M. Flack, MD, MPH, FAHA, MACP, FASH

In re: Valsartan, Losartan, and Irbesartan Products Liability Litigation

Pages, Lines	Change:	Reason
Page 11, Line 2	“work address is 7 Southern Illinois”	Transcription error
Page 33, Line 1	“My understanding of your question is that you did ”	Clarification
Page 33, Line 2	“ you get all of the information”	Clarification
Page 53, Line 20	“By the time I write a report I have read it and”	Clarification
Page 53, Line 23	“that, but there as have been many”	Clarification
Page 54, Line 2	“just a that I write”	Transcription error
Page 61, Line 18	“where I did, again an , National Institutes”	Transcription error
Page 61, Line 19	“postdoctoral fellowship, in cardiovascular”	Clarification
Page 65, Line 5	“perspective, I had have received”	Transcription error
Page 66, Line 23	“the FDA cracked down the on them -- also,”	Clarification
Page 67, Line 1	“ and in who writes what prescriptions”	Transcription error
Page 67, Line 18	“and give promotion promotional talks”	Clarification
Page 74, Line 18	“get but about \$25,000 in that. So”	Clarification
Page 75, Line 5	“drug better. That's where what ”	Clarification
Page 75, Line 6	“our study was, is a study to”	Clarification
Page 86, Line 22	“there to employ promote subscribing”	Clarification
Page 104, Line 12	“ or in combination”	Transcription error
Page 105, Line 10	“not true. This is basically Go back”	Clarification

Page 108, Line 7	“diabetes mellitus, which is common diabetes mellitus - which is common”	Clarification
Page 108, Line 8	“physical activity, certain intakes of physical activity - certain intakes with”	Clarification
Page 112, Line 23	“cycles of NHANES data, that's”	Clarification
Page 113, Line 5	“bias by the weight of the sample how they weight their sampling”	Clarification
Page 113, Line 6	“and so you”	Clarification
Page 127, Line 7	“dive to too in depth”	Transcription error
Page 129, Line 11	“that's there's a difference”	Transcription error
Page 132, Line 12	“is fairly pretty good”	Transcription error
Page 144, Line 9	“Well, you can't say it is biologically plausible, therefore it causes cancer in humans, which”	Clarification
Page 152, Line 24	“It could be originate”	Clarification
Page 153, Line 1	“the ureters uterus to”	Transcription error
Page 160, Line 17	“you basically ex-train”	Transcription error
Page 167, Line 12	“cancer is firstly virtually nonexistent.”	Transcription error
Page 178, Line 12	“There is zero problem with finding a”	Clarification
Page 180, Line 9	“risk and caused cancer”	Transcription error
Page 185, Line 17	“plausible hypothesis -- a synthesis”	Clarification
Page 185, Line 18	“no confirmatory data in humans that are — expands into the despite studying”	Clarification
Page 185, Line 22	“well below what is”	Clarification
Page 189, Line 21	“the 10-milligram -- the 160-milligram pill has probably 10 micrograms”	Clarification
Page 190, Line 2	“medicine and because”	Clarification
Page 198, Line 4	“is a little more normal on”	Transcription error
Page 205, Line 21	“general journal editor.”	Transcription error
Page 210, Line 10	“Christine Lang Laine would”	Transcription error

Page 210, Line 8	“ the Journal of The Annals of”	Clarification
Page 210, Line 9	“Internal Medicine Journal does”	Clarification
Page 214, Line 9	“ are for both cardiovascular”	Transcription error
Page 219, Line 7	“Ernesto Shiff Schiffrian, one”	Transcription error



John M. Flack, MD, MPH, FAHA, MACP, FASH

KM Harris, Notary Public.
This, the 2nd day of November, 2021.

My Commission Expires:

